UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
Newark Vicinage

ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated, *Plaintiff,* v. ELI LILLY AND COMPANY, NOVO NORDISK INC., SANOFI-AVENTIS U.S. LLC, CVS HEALTH CORPORATION, CAREMARKPCS HEALTH LLC, CAREMARK LLC, CAREMARK RX LLC, EXPRESS SCRIPTS HOLDING COMPANY, EXPRESS SCRIPTS INC., MEDCO HEALTH SOLUTIONS INC., UNITED HEALTH GROUP INCORPORATED, UNITED HEALTHCARE SERVICES INC., OPTUM INC., OPTUMRX HOLDINGS, LLC, and OPTUMRX INC., *Defendants.*	CIVIL ACTION NO.

CLASS ACTION COMPLAINT

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC" or "Plaintiff"), on behalf of itself and all others similarly situated, for its complaint against defendants Eli Lilly and Company ("Eli Lilly"), Novo Nordisk Inc. ("Novo Nordisk") and Sanofi-Aventis U.S. LLC ("Sanofi") (together, the "Defendant Drug Manufacturers"), CVS

Health Corporation, CaremarkPCS Health, L.L.C., Caremark L.L.C., and Caremark Rx L.L.C. (collectively, "CVS Caremark"), Express Scripts Holding Company, Express Scripts, Inc., and Medco Health Solutions, Inc. (collectively "Express Scripts"), and United Health Group Incorporated, United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. ("OptumRx") (together, the "Defendant PBMs"), alleges the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. Plaintiff brings this action on behalf a proposed class of direct purchasers of analog Insulin from the Defendant Drug Manufacturers against those manufacturers and the Defendant PBMs to recover overcharges due to the Defendant Drug Manufacturers' artificial inflation of prices in the United States for the analog Insulin medications at issue in this complaint, which are Humalog, Basaglar, Fiasp, Novolog, Levemir, Tresiba, Apidra, Lantus, and Toujeo ("Insulin" or "Insulin products").

2. This action arises out of schemes by the Defendant Drug Manufacturers to maintain and/or increase the volume- and dollar-amount of their Insulin sales through: (a) the payment of bribes and kickbacks to the PBM Defendants in the form of unprecedented rebates, fees, discounts, or other payments or financial incentives in exchange for inclusion and/or favorable placement of the Defendant

Drug Manufacturers' respective Insulin products on the Defendant PBMs' formularies; and (b) the concealment and fraudulent statements in connection with the scheme. The Defendants' respective schemes had the purpose and/or effect of eliminating a check on the Defendant Drug Manufacturers' ability to aggressively increase their list prices, and were carried out by aggressively raising their list prices. Consequently, both to generate the bribe and kickback money they paid to Defendant PBMs, and after the bribes and kickbacks were paid, the Defendant Drug Manufacturers aggressively increased their Insulin list prices far beyond what they would have (and could have) done absent the scheme.

3. Over the last several years, the targets of Defendant Drug Manufacturers' bribes, *i.e.*, the Defendant PBMs, have consolidated and grown to manage and administer prescription drug benefits for the vast majority of Americans. Together, the three largest PBMs (defendants CVS Caremark, Express Scripts, and OptumRx) control over 85% of the market and possess the market power of more than 200 million people. As alleged in more detail below, private and public health plans and insurers around the country, including ones who have contracted with the United States or one of its agencies, have delegated to the Defendant PBMs day-to-day authority and virtually exclusive control over: (a) the negotiation of rebates with drug makers; (b) the flow of moneys to pharmacies and health plans (and therefore how much the Defendant PBMs can keep for themselves); and (c) the structure and

composition of formularies, which are a significant factor in influencing purchasing patterns for drugs. Thus, Defendant PBMs have influence and/or control over which drugs will be covered by the health plan/insurer clients that they serve, and thus which drugs will be prescribed and thus purchased. This makes the Defendant PBMs natural targets for Defendant Drug Manufacturers' bribes.

4. The effect of the Defendant Drug Manufacturers' bribes and kickbacks to the Defendant PBMs has been to corrupt the market policing mechanisms that the Defendant PBMs would otherwise perform, causing significant supra-competitive pricing inflation and market-wide consumer harm. In the past, PBMs would penalize manufacturers who raised their prices too much by giving formulary preference to lower-priced drugs, which benefitted the PBM's health-plan clients. Such conduct worked to limit price increases because a manufacturer that raised its prices too much risked adverse formulary treatment. However, the Defendant Drug Manufacturers' bribes coopted the Defendant PBMs to favor higher-priced drugs (to their clients' detriment) because Defendant PBMs retained a significant portion of the rebates and did not pass to the health plan/insurer clients many of the other fees that they received from the Defendant Drug Manufacturers. This created a conflict of interest, because: (a) the health plan's interest is in promoting the lowest-priced drugs and (b) the PBMs' interest is in generating the highest amount of rebates and fee payments, even if it results in their health plans (and patients and purchasers) being

pushed to higher-priced drugs. Indeed, because of this conflict of interest the Defendant PBMs are not simply indifferent to the Defendant Drug Manufacturers' large annual price increases, but they actually benefitted from such increases because the price increases inflated the amount of the bribes and kickbacks that the Defendant PBMs received from the Defendant Drug Manufacturers. This conflict has made the Defendant PBMs natural targets for Defendant Drug Manufacturers' bribes and kickbacks because the payments incentivized them to favor the high-priced Insulin products.

5. Under several federal and state anti-kickback and bribery laws it is and was illegal for the Defendant Drug Manufacturers to pay rebates, fees, and other moneys to Defendant PBMs in return for formulary placement. This is especially so because some or all such moneys did not flow downstream to the insurers/health plans (and/or their members) as discounts. The Department of Health and Human Services (the agency responsible for implementing one federal anti-kickback statute) has made it clear that payments for formulary placement are not exempted under that statute as "discounts."

6. Furthermore, Defendant PBMs owe a duty of fidelity to their health plan/insurance clients (and their participants and beneficiaries), because of: (a) the contractual relationships between the Defendant PBMs and their health plan/insurer clients; and (b) the Defendant PBMs' position as agents, trustees, employees, and/or

contractors for their health plan/insurer clients.

7. In addition to a duty of fidelity, Defendant PBMs have a fiduciary duty to their health plan/insurance clients (and their participants and beneficiaries).

8. In the past, when there were multiple brand drugs indicated for the same use, PBMs awarded formulary placement to the manufacturers who charged the lowest prices for their drugs and/or who restricted their list price increases. That was consistent with their health plan/insurer clients' interests. Indeed, that is a fundamental role and skill that PBMs market to their clients: their purported ability to drive hard bargains to not only negotiate rebates, but also curb the growth of drug prices. As a consequence of the PBM's placement of a manufacturer's drug in a favorable position on the formulary, the drug manufacturer enjoys increased usage and thus sales for its product.

9. However, the Defendant Drug Manufacturers' payment of bribes and kickbacks relating to Insulin caused the Defendant PBMs to: (a) favor higher-priced Insulin over lower-priced Insulin on the formulary; (b) remove the historical curbs or checks on list price increases; and (c) encourage and accelerate Defendant Drug Manufacturers' list price increases for their Insulin. It was improper and illegal under one or more state and federal laws for the Defendant Drug Manufacturers to pay bribes and kickbacks to Defendant PBMs to act contrary to the interests of their health plan/insurer clients and to conceal same. Defendant Drug Manufacturers'

bribes and kickbacks, and accompanying fraud in concealing that Defendant Drug Manufacturers' list price increases were part and parcel of the bribes and kickbacks, enabled and caused tremendous Insulin list price increases that would not have happened absent the misconduct alleged herein.

10. Plaintiff (and the other class members) are direct purchasers of Defendant Drug Manufacturers' Insulin products. They buy directly from the Defendant Drug Manufacturers at the list price. They were overcharged by Defendants' respective schemes because absent the Defendants' conduct they would have paid lower list prices for the Insulin products they purchased. Plaintiff, on behalf of itself and other direct purchasers, seeks recovery of those overcharges.

11. Plaintiff's allegations are based on its own experience; personal knowledge and research; the research of counsel; publicly available articles, studies, reports, and other sources; a reasonable inquiry under the circumstances; and on information and belief.

II. PARTIES

12. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, NY. During the Class period, as defined below, Plaintiff purchased analog Insulin directly from Defendant Drug Manufacturers and was injured as a result of Defendants' unlawful conduct.

13. Defendant Eli Lilly and Company ("Eli Lilly" or "Lilly") is a corporation organized and existing under the laws of the State of Indiana. Eli Lilly's principal place of business is Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly manufactures Humalog and Basaglar, which are used for the treatment of diabetes. Eli Lilly's revenues from Humalog in 2016 were $2.84 billion. Its revenues from Humalog were $1.5 billion in 2013 and $1.7 billion in 2015.

14. Defendant Novo Nordisk, Inc. ("Novo Nordisk") is a Delaware corporation having its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. Novo Nordisk manufactures Fiasp, Novolog, Levemir, and Tresiba, which are used for the treatment of diabetes. Novo Nordisk's revenues from the sale of Novolog were $3.03 billion in 2016 and over $2 billion in 2014 and 2015. Revenues from Levemir were $955 million in 2013, and $1.3 billion in 2014 and 2015. Sales to diabetic patients are such a critical part of Novo Nordisk's business, that its 2015 Annual Report's cover page stated in bold letters, "Why Do So Many People in Cities Get Diabetes?"

15. Defendant Sanofi-Aventis U.S. LLC ("Sanofi") is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi manufactures Apidra, Lantus, and Toujeo, which are used for the treatment of diabetes. Sanofi's revenues from Lantus were $6.98 billion in 2016 and over $4 billion in each year since 2013. Sanofi's SEC

Form 20-F for the year 2015 notes that "Lantus is particularly important; it was the Group's leading product . . . representing 17.2% of . . . net sales[.]"

16. Defendant CVS Health Corporation is a retail pharmacy and healthcare company headquartered at One CVS Drive, Woonsocket, Rhode Island 02895 and incorporated in Delaware. CVS Health Corporation, through its Pharmacy Services Segment, provides pharmacy benefit management services to various health insurance entities on behalf of nearly 90 million health plan participants. In its 2016 Annual Report, CVS Health Corporation repeatedly referred to itself as a PBM, stating that it is "the largest integrated pharmacy health care provider in the United States" and that it "provides a full range of pharmacy benefit management services." In its 2016 Annual Report, CVS Health Corporation further stated that one of its three business segments is its Pharmacy Services Segment, which provides "a full range of pharmacy benefit management [] solutions, including plan design offerings and administration, formulary management," and that approximately 60% of its 2016 revenues were derived from its Pharmacy Services Segment.

17. Defendant CaremarkPCS Health, L.L.C., a Delaware limited liability corporation, formerly known as Caremark PCS Health, L.P., was incorporated in 2002 and is headquartered at 750 West John Carpenter Freeway, Irving, Texas 75039. CaremarkPCS Health, L.L.C., d/b/a CVS Caremark, provides pharmacy benefit management services to various health insurance entities. CaremarkPCS

Health, L.L.C. is a wholly owned subsidiary of CVS Health Corporation.

18. Defendant Caremark, L.L.C., a California limited liability company, is headquartered at 2211 Sanders Road, Northbrook, Illinois 60062-6128. Caremark, L.L.C. offers pharmacy benefit management services to various health insurance entities. Caremark, L.L.C. is a wholly owned subsidiary of CVS Health Corporation.

19. Defendant Caremark Rx, L.L.C., a Delaware limited liability company, is headquartered at 211 Commerce Street, Nashville, Tennessee 37201. Caremark Rx, L.L.C. provides pharmacy benefit management services. Caremark Rx, L.L.C. is a wholly owned subsidiary of CVS Health Corporation. Caremark Rx, L.L.C. is the parent of Defendant CVS Health Corporation's pharmacy services subsidiaries and is the immediate or indirect parent of many pharmacy benefit management subsidiaries, including Defendant CaremarkPCS Health, L.L.C.

20. Defendant CaremarkPCS Health, L.L.C. and Caremark L.L.C. are agents and/or alter egos of Defendant Caremark Rx, L.L.C., and Defendant Caremark Rx, L.L.C. is an agent and/or alter ego of Defendant CVS Health Corporation. For example, Jonathan C. Roberts, CEO of Caremark Rx, L.L.C., is Executive Vice President and Chief Operating Officer of CVS Health Corporation. Thomas S. Moffatt, Secretary of Caremark Rx, L.L.C. and Caremark, L.L.C., is a Vice President, Assistant Secretary, and Assistant General Counsel at CVS Health Corporation. Anne E. Klis, CEO of Caremark, L.L.C., is Vice President of

Professional Practice and Training at CVS Health Corporation. Daniel P. Davison, CEO of CaremarkPCS Health, L.L.C., is Senior Vice President of Finance at CVS Health Corporation. Melanie K. Luker, Assistant Secretary of CaremarkPCS Health, L.L.C., is Manager of Corporate Services at CVS Health Corporation.

21. For purposes of clarity, Plaintiff herein collectively refers to CVS Health Corporation, CaremarkPCS Health, L.L.C., Caremark L.L.C., and Caremark Rx L.L.C. as "CVS Caremark."

22. Defendant Express Scripts Holding Company is a full-service pharmacy benefit management and specialty managed care company headquartered at One Express Way, St. Louis, Missouri, 63121 and incorporated in Delaware. Express Scripts Holding Company provides pharmacy benefit management services through its wholly-owned subsidiaries to various health insurance entities on behalf of 83 million plan participants. In its 2016 Annual Report, Express Scripts Holding Company repeatedly referred to itself as a PBM, stating that it is "the largest stand-alone pharmacy benefit management [] company in the United States" and that it "provides integrated pharmacy benefit management services." In its 2016 Annual Report, Express Scripts Holding Company further stated that one of its two business segments is the PBM segment and that 96.2% of its 2016 revenues were derived from its PBM operations.

23. Defendant Express Scripts, Inc. is a pharmacy benefit manager

headquartered at One Express Way, St. Louis, Missouri 63121 and incorporated in Delaware. Express Scripts, Inc. is a subsidiary of Express Scripts Holding Company. Express Scripts, Inc. provides pharmacy benefit management services to various health insurance entities.

24. Defendant Medco Health Solutions, Inc. is a pharmacy benefit manager headquartered at 100 Parsons Pond Road, Franklin Lakes, New Jersey 07417 and organized under Delaware law. Medco Health Solutions, Inc. is a subsidiary of Express Scripts Holding Company. Medco Health Solutions, Inc. provides pharmacy benefit management services to various health insurance entities.

25. Medco Health Solutions, Inc. and Express Scripts, Inc. are agents and/or alter egos of Express Scripts Holding Company. For example, David Queller, President of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Senior Vice President of Sales & Account Management at Express Scripts Holding Company. Christine Houston, a Vice President at both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Executive Vice President and Chief Operations Officer at Express Scripts Holding Company. John Mimlitz, a Vice President at both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Vice President of Tax at Express Scripts Holding Company. Timothy Smith, a Vice President and Treasurer of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Corporate Treasurer and Vice President of Finance and Indirect Procurement at

Express Scripts Holding Company. Rod Fahs, the Assistant Secretary of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Assistant General Counsel at Express Scripts Holding Company. Christopher McGinnis was a Vice President at Express Scripts, Inc., and also a Vice President and Chief Accounting Officer of Express Scripts Holding Company. Martin Akins, the only member of the Board of Directors of Express Scripts, Inc. and the only member of the Board of Directors of Medco Health Solutions, Inc., and Secretary of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Senior Vice President, General Counsel, and Corporate Secretary of Express Scripts Holding Company. All of the officers of Medco Health Solutions, Inc. are also officers of Express Scripts, Inc.

26. For purposes of clarity, Plaintiff herein collectively refers to Express Scripts Holding Company, Express Scripts, Inc., and Medco Health Solutions, Inc. as "Express Scripts."

27. Defendant UnitedHealth Group Incorporated is headquartered at 9900 Bren Road East, Minnetonka, Minnesota and incorporated in Delaware. UnitedHealth Group Incorporated has two main divisions: UnitedHealthcare, which provides health benefits, and Optum, which provides health services, including pharmacy benefit management services. According to its 2016 Annual Report, "UnitedHealthcare utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze cost trends, manage pharmacy

benefits, work with care providers more effectively and create a simpler consumer experience." The 2016 Annual Report further states, "OptumRx provides a full spectrum of pharmacy care services to more than 65 million people in the United States through its network of more than 67,000 retail pharmacies and multiple home delivery facilities throughout the country." In 2016, approximately one-third of the overall revenues of UnitedHealth Group Incorporated came from OptumRx, Inc., and OptumRx, Inc.'s revenues almost doubled between 2014 and 2016, from $32 billion to $60 billion.

28. Defendant United Healthcare Services, Inc. is headquartered at 9700 Health Care Lane, Minnetonka, Minnesota and incorporated in Minnesota. UnitedHealthcare Services, Inc. is a subsidiary of UnitedHealth Group Incorporated and provides pharmacy benefit management services through its subsidiaries to various health insurance entities. According to Exhibit 21.1 to UnitedHealth Group Incorporated's 2016 Securities and Exchange Commission Form 10-K, UnitedHealthcare Services, Inc. also does business as Optum, Inc.

29. Defendant Optum, Inc. is a PBM headquartered at 11000 Optum Circle, Eden Prairie, Minnesota and incorporated in Delaware. Optum, Inc. is a subsidiary of UnitedHealthcare Services, Inc., which provides pharmacy benefit management services through its subsidiaries to various health insurance entities on behalf of more than 65 million plan participants.

30. Defendant OptumRx Holdings, LLC, a Delaware limited liability corporation, is headquartered at 2300 Main Street, Irvine, California. OptumRx Holdings, LLC is a PBM and a subsidiary of Optum, Inc. OptumRx Holdings, LLC provides pharmacy benefit management services through its subsidiaries to various health insurance entities.

31. Defendant OptumRx, Inc. is a PBM headquartered at 2300 Main Street, Irvine, California and incorporated in California. OptumRx, Inc. is a subsidiary of OptumRx Holdings, LLC. OptumRx, Inc. changed its name from Prescription Solutions, Inc. to OptumRx, Inc. in 2012. OptumRx, Inc. provides pharmacy benefit management services to various health insurance entities.

32. Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. are agents and/or alter egos of United Healthcare Services, Inc. United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. are agents and/or alter egos of UnitedHealth Group Incorporated. OptumRx Holdings, LLC and OptumRx, Inc. are agents and/or alter egos of Optum, Inc. OptumRx, Inc. is an agent and/or alter ego of OptumRx Holdings, LLC. For example, Larry Renfro, CEO of Optum, Inc., is Vice Chairman, Office of the Chief Executive, at UnitedHealth Group Incorporated. Tom Roos, Senior Vice President and Chief Accounting Officer of UnitedHealth Group Incorporated, is Chief Financial Officer of UnitedHealthcare Services, Inc. Timothy Alan Wicks, Chief Financial Officer and Executive Vice

President of Optum, Inc. is also a director of OptumRx, Inc.

33. For purposes of clarity, Plaintiff herein collectively refers to United Health Group Incorporated, United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. as "OptumRx."

34. The wrongful acts alleged to have been done by Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx were authorized, ordered, or done by their respective directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of their respective affairs.

III. JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because the Plaintiff's claims arise under federal law and under 18 U.S.C. § 1964(c); this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*.

36. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because each Defendant transacts business in, is found in, and/or has agents in the District of New Jersey, and because some of the actions giving rise to this complaint took place within this district.

37. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or

committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. FACTUAL ALLEGATIONS

A. THE PRESCRIPTION DRUG SELECTION AND DISTRIBUTION SYSTEM

1. The Prescription Drug Distribution Chain

38. Pharmaceutical companies develop, manufacture, market, and sell prescription drugs. At the beginning of the prescription drug distribution chain, pharmaceutical companies sell prescription drugs to drug wholesalers (such as Plaintiff), which then re-sell the drug products to a pharmacy or other drug dispensary, who then dispense the drug to the patient. The drug is ultimately paid for by: (a) the patient (if it is a cash patient lacking insurance), (b) a third-party payor (such as a commercial or government insurer or health plan if they cover the drug cost); or (c) a combination of the patient and health plan, if the patient's health plan requires some type of co-payment.

39. Wholesalers pay directly to Defendant Drug Manufacturers the list price for Insulin. The list price is sometimes called Wholesale Acquisition Cost ("WAC"). WAC is the published list price paid by Plaintiff and the other direct

purchaser class members. The direct purchaser may obtain a small percentage discount off of WAC for paying its invoice early.

40. Average Wholesale Price ("AWP") is an "index" price that is a calculated derivative of WAC, and is used by PBMs to determine pharmacy reimbursements for sales to insured patients. It is typically set as WAC plus 20%.

41. The price that patients pay for drugs like Insulin at the pharmacy counter varies based on whether they have insurance and the nature of their coverage. Uninsured patients pay the "cash" price, which is a price that has been marked-up from the pharmacist's purchase or acquisition cost.

42. For those drugs which are covered by insurance, patients in high "deductible" insurance plans will pay the cash price for each prescription until they meet the deductible amount under their insurance or health plan, at which point the insurer or health plan pays for some or all of the remaining covered purchases over the course of the year. Separate and aside from deductibles, patients often have "coinsurance obligations," pursuant to which the health plan or insurer will pay for the majority of the prescription cost, but the patients are required to pay part of the price referred to as the "co-pay" amount. Patients pay either a fixed percentage of the drug's cost, or a set dollar amount depending on the drug's formulary placement and whether the drug is preferred or not.

43. Formularies are lists of drugs that are covered by insurance. Most

formularies have multiple tiers of coverage. The formulary tier in which a drug is placed impacts whether a drug is covered and what co-pay amounts the patient will be required to pay at the pharmacy counter. Branded drugs that are covered by a health plan or insurer are typically covered in Tier 2 or higher.

44. A health plan or insurer's cost for a prescription is impacted by various factors. Once an insurer's obligations begin under a high-deductible plan, the health plan will directly or indirectly reimburse the pharmacist for a patient's prescription based on an "ingredient cost" plus a dispensing fee. For patients in "coinsurance" plans, the reimbursement amount that the health plan pays the pharmacist will be offset or reduced by the co-pay amount that the patient pays directly to the pharmacist. The health plan or insurer's final or "net" costs for a prescription may be reduced by rebates from drug manufacturers that the health plan negotiated directly with the manufacturer or which were negotiated by a PBM (to the extent the PBM actually passes the rebates down to the health plan).

45. While the rebates that health plans receive from drug manufacturers help to reduce a drug's net price, those rebates never equal 100% of the prescription cost. Consequently, all else being equal, a health plan or insurer will always benefit from a lower list price than an increased rebate, and obversely, health plans and insurers are always worse off from an increase in list prices, regardless of the fact that they receive rebates. For example, if a health plan receives a 10% rebate on a

drug with a $200 list price, the health plan's net price (putting aside the effect of patient co-pay contributions, taxes and various fees) equals $180. If the list price drops down $100 (and there is no change in the rebate percentage level), the health plan's net price (putting aside co-pay amounts, taxes and fees) equals $90 ($100 minus $10 rebate). If the price instead increases $100 (and the 10% rebate stays the same) then the health plan's net price equals $270 ($300 minus $30 rebate).

46. As the foregoing reflects, while the rebates help to blunt the full impact of a price increase, the rebates never fully offset the price increase. Consequently, it is always in the health plan's interest to curb drug prices by trying to drive patients to lower-priced equivalent drugs and/or discouraging drug makers from raising prices. The same is true for cash patients, patients in high-deductible plans, and patients whose co-pay is set as a percentage of the drug's list price.

2. PBMs' Role In the Drug Selection and Dispensing Process

47. With the exception of their mail-order pharmacy business, PBMs are not buyers of drugs. PBMs operate as middlemen who are hired by various types of insurers and health plans to design, manage, and administer prescription drug benefit programs. The PBMs' functions frequently include: (a) negotiating rebates on the health plan/insurers' drug purchases with drug manufacturers, (b) designing and revising the health plan/insurers' benefit rules (such as copay levels, deductibles, and formulary specifics) and determining coverage eligibility and copayments, and

(c) designing, developing and managing formularies and formulary compliance programs.[1]

48. Regardless of the nominal control that some insurers and health plans may formally retain over these functions, in reality many (if not most) of the insurers and health plans have delegated to PBMs the day-to-day control over these functions.

a) PBMs' Role In Negotiating Rebates With Manufacturers

49. PBMs became a major force in the late 1980s, expanding from pharmacy claims processing to a business model that forced drug manufacturers to engage in price negotiation in several drug categories. PBMs typically selected one brand among several brand drugs in a therapeutic class as the "preferred" choice and negotiated payments from that manufacturer called "rebates." So long as those rebates were passed back to the health plan, that approach could lower the net cost of that brand to health plans.[2]

50. PBMs gained even more prominence — and recognition from the federal government — in 2003 with the passage of the Medicare Modernization Act

[1] Robert F. Atlas, "The Role of PBMs In Implementing The Medicare Prescription Drug Benefit," Medicare Drug Benefit (Oct. 28, 2004), at W4-505-506, *available at* https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.W4.504.

[2] Health Affairs, "Prescription Drug Pricing: Pharmacy Benefit Managers," Health Policy Brief Series (Sept. 2017) at p. 1.

(MMA). This law implemented the Medicare Part D outpatient drug benefit using plans that competed for customers based on their advertised ability to negotiate favorable drug prices, create formularies, and hold down premiums. PBMs generally represent the Part D plans in these negotiations.[3]

51. PBMs' effectiveness as negotiators with pharmaceutical manufacturers grew as PBMs grew in size and covered lives they represented in negotiations. The more covered lives (insured patients) represented by a PBM, the more likely that manufacturers will offer rebates in return for preferred formulary coverage, which in turn would cause increased sales of the manufacturer's drug. According to the PBMs' trade association — the Pharmaceutical Care Management Association ("PCMA") — as of January 2019, PBMs administered prescription drug benefits for more than 266 million Americans.[4] In 2018, the top six PBMs handled more than 95% of total U.S. prescription claims.[5]

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[3] *Id.*

[4] PCMA, "Increased Competition Key to Reducing Prescription Drug Costs" (Jan. 28, 2019), *available at* https://www.pcmanet.org/pcma-offers-policy-solutions-to-reduce-prescription-drug-costs/.

[5] "CVS, Express Scripts, and the Evolution of the PBM Business Model," Drug Channels (May 29, 2019), *available at* https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html. CVS Health Corporation, through its Pharmacy Services Segment, provides pharmacy benefit management services to various health insurance entities on behalf of nearly 90 million health plan participants, including plan design and administration, formulary management. Express Scripts Holding Company is a full-service PBM and specialty managed care company which provides pharmacy benefit management services through its

52. Because increased size gives an individual PBM increased negotiating leverage there has been dramatic consolidation in the PBM industry during the past decade. In 2012, when the Federal Trade Commission approved Express Scripts's acquisition of Medco, the agency found there were "at least ten significant competitors" in the PBM segment.[6] However, by 2014, the top three PBMs (the Defendant PBMs) managed over 180 million lives — about 80 percent of the total number of patients covered by PBMs, evidencing recent consolidation.[7] According to a May 2019 industry article,[8] at the end of 2018, the Defendant PBMs continued

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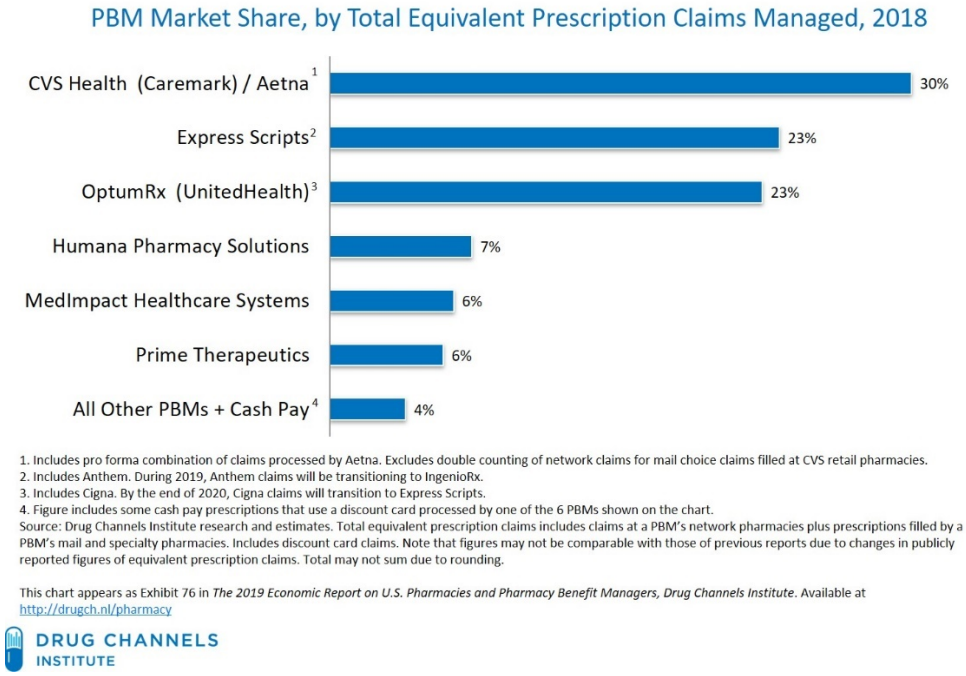
wholly-owned subsidiaries to various health insurance entities on behalf of 83 million plan participants. In its 2016 Annual Report, Express Scripts Holding Company repeatedly referred to itself as "the largest stand-alone [PBM] company in the United States" and that it "provides integrated pharmacy benefit management services." Medco Health Solutions, Inc. is a subsidiary of Express Scripts Holding Company. Optum, Inc. provides pharmacy benefit management services through its subsidiaries to various health insurance entities on behalf of more than 65 million plan participants. Prime Therapeutics, LLC is owned by fourteen Blue Cross and Blue Shield health insurance entities. Prime provides pharmacy benefit management services to those fourteen Blue Cross and Blue Shield health insurance entities on behalf of more than 20 million health plan participants.

[6] Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210 (Apr. 2, 2012), at 2, *available at* https://www.ftc.gov/sites/default/files/documents/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express./120402expressscripts.pdf.

[7] Health Affairs, "Prescription Drug Pricing: Pharmacy Benefit Managers," Health Policy Brief Series (Sept. 2017) at p. 2.

[8] "CVS, Express Scripts, and the Evolution of the PBM Business Model," Drug Channels (May 29, 2019), *available at* https://www.drugchannels.net/2019/05/cvs-

to control over 75% of the covered lives:



53. In contrast, the market for health plans and insurers is much less concentrated, with the 25 largest companies accounting for less than two-thirds of the business in 2014.[9] For brand name drug manufacturers, 13 companies account for 90% of the U.S. market.[10] Thus, it is typical to have a large PBM negotiating with several drug manufacturers on behalf of a large number of relatively small

express-scripts-and-evolution-of.html.

[9] Evi Heilbrunn, "Top Health Insurance Companies," U.S. NEWS & WORLD REPORT (Nov. 5, 2014), *available at* https://health.usnews.com/health-news/health-insurance/articles/2013/12/16/top-health-insurance-companies; Charles Roehrig, "The Impact of Prescription Drug Rebates on Health Plans and Consumers", Altarum (Apr. 2018) at p. 8, *available at* https://altarum.org/publications/impact-prescription-drug-rebates-health-plans-and-consumers.

[10] *Id.*

health plans.

54. One of the key functions that PBMs perform for their clients is to negotiate rebates with drug manufacturers. However, rather than negotiating agreements with drug manufacturers separately and individually for each of their health plan and insurer clients, PBMs typically use their combined clout to negotiate a master agreement on behalf of all their clients. As a result, in the world of drug price negotiation, market power is most highly concentrated among PBMs, and in particular the Defendant PBMs, who have more negotiating leverage than any individual drug manufacturer or health plan on either side of a transaction.

55. Because the Defendant PBMs can negotiate better rebate deals than health plans/insurers can get on their own, they are in a strong position when negotiating contract terms and conditions with the health plans/insurers they represent. While a PBM is nominally "hired by" and "working for" a particular health plan, the Defendant PBMs are actually in the driver's seat. While health plans/insurers may technically have the right to independently control rebate negotiations, they have delegated that power to the Defendant PBMs to exercise during the course of their relationship.

56. For example, Express Scripts's standard, uniform contract provides that it be given full and complete control to negotiate with drug makers for the insurer/health plan client, that the client will forego any right to directly negotiate

with drug makers, and if the client does negotiate on its own then the PBM may terminate the relationship or the client may have to forego all rebates:

> Sponsor acknowledges that it may be eligible for Rebate amounts under this Agreement only so long as Sponsor, its affiliates, or its agents do not contract directly or indirectly with anyone else for discounts, utilization limits, rebates or other financial incentives on pharmaceutical products or formulary programs for claims processed by ESI pursuant to the Agreement, without the prior written consent of ESI. . . . To the extent Sponsor knowingly negotiates and/or contracts for discounts or rebates on claims for Covered Drugs without prior written approval of ESI, such activity will be deemed to be a material breach of this Agreement, entitling ESI to suspend payment of Rebate amounts hereunder and to renegotiate the terms and conditions of this Agreement.[11]

Thus, Express Scripts will work for an insurer/health plan only so long as the sponsor/payor agrees to: (a) abstain from using its right to negotiate rebates for its purchases without Express Scripts's written permission; and (b) give Express Scripts *de facto* control over rebate negotiations.

57. Similarly, as discussed above, Defendant PBMs generally represent the private plans who handle the outpatient drug benefits for Medicare Part D patients pursuant to the 2003 MMA. The MMA contains a noninterference provision, section 1860D-11(i) (42 U.S.C. 1395w-111(i)), which restricts direct government

[11] Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (February 27, 2015), *available at* http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf.

involvement in Part D price negotiations.[12] This is further reflection and demonstration of the Defendant PBMs' exclusive control over price negotiations for their clients**.**

b) PBMs' Role In Designing Formularies

58. Formularies are a central tool that payors use in designating, managing and publicly identifying the extent of the coverage and benefits they provide to their members. Because formulary coverage impacts how much a patient pays for a drug, formularies can be used to steer patients toward certain drugs over others, and that is one of the key purposes and functions of formulary design, implementation and management.

59. While some PBM clients have formal, nominal control over the structure of the formularies they implement, they usually retain the PBMs to administer the formularies and give the PBM contractual authority to make day-to-day changes, unless the health plan takes the affirmative step of electing not to implement any such change. Such is the case with the Defendant PBMs. For example, the Express Scripts contract template provides that:

> "Formulary" means the list of FDA-approved prescription drugs and supplies developed by ESI's Pharmacy and Therapeutics Committee and/or customized by Sponsor, and which is selected and/or adopted by Sponsor. The drugs and supplies included on the Formulary will be modified by ESI from time to time as a

[12] Health Affairs, "Prescription Drug Pricing: Pharmacy Benefit Managers," Health Policy Brief Series (Sept. 2017) at p. 2.

> result of factors, including, but not limited to, medical appropriateness, manufacturer Rebate arrangements, and patent expirations. Additions and/or deletions to the Formulary are hereby adopted by Sponsor, subject to Sponsor's discretion to elect not to implement any such addition or deletion through the Set-Up Form process, which such election shall be considered a Sponsor change to the Formulary.[13]

60. Most health plan and insurer clients rely upon a Defendant PBM's formulary recommendations. Indeed, the Express Scripts contract template provides that Express Scripts's additions and/or deletions to the formulary are automatically assumed to be adopted by the health plan sponsor, unless the sponsor takes the affirmative step of electing not to implement any such addition or deletion through the set-up form process. A well-known pharmacy-benefits consultant, David Dross, noted during a presentation that health plans "don't have clinicians on staff, they don't even question their PBM's formulary, much less design their own."[14] The PCMA — the PBM trade association — has testified to the Pennsylvania House of Representatives that even sophisticated insurers and health plans rely on PBMs to manage their drug benefit.[15] The Defendant PBMs' contractual authority to make

[13] Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (Feb. 27, 2015), *available at* http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf.

[14] "Employers Should 'Ask the Hard Questions' About PBM Formularies," HEALTH BUSINESS DAILY (Dec. 19, 2014), *available at* https://www.coleridgelaw.com/archive/nhpw120814-03.

[15] Letter from PCMA to the Matthew E. Barker, Pennsylvania House of

changes to the formulary list, combined with many clients' reliance on the Defendant PBMs' formulary recommendations and decisions, gives the Defendant PBMs substantial day-to-day control in managing their clients' formularies.

61. The Defendant PBMs' control over formulary decisions is related to (and a necessary predicate of) their ability to negotiate manufacturer rebates, because manufacturers pay rebates based on the Defendant PBMs' ability to deliver formulary placement for their drugs. Because favorable formulary status is likely to increase (or at least maintain) a drug's usage and sales, and formulary exclusion (or a downgrade in formulary position) is likely to reduce a drug's usage and sales, manufacturer rebates are often (if not always) conditioned on a drug's formulary coverage. Thus, the amount of the rebates that a drug manufacturer will pay will be impacted by a PBM's ability to deliver formulary status that will increase drug sales. As Cottingham & Butler (a national insurance broker) noted in a client presentation, PBMs have "unilateral control . . . over formularies and tiering — driving greater profits for PBMs through rebates[.]"[16]

62. In the past, PBMs generally devised and managed what are known as "open" formularies: formularies that offer varying degrees of plan coverage and

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Representatives, House Comm. On Health (Aug. 28, 2013).

[16] Nancy Daas, *Prescription Drug Plan Strategies*, Cottingham & Butler (2017), *available at* http://www.cottinghambutler.com/wp-content/uploads/2017/03/Prescription-Drug-Strategies.pdf.

benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies compete to have their drugs placed by PBMs into the most favorable formulary tier possible. Like open formularies, "closed" formularies provide tiered benefits, but unlike open formularies, they restrict the overall number of drugs that are entitled to receive any plan prescription drug benefit. In the 2010s, PBMs, including the Defendant PBMs, started shifting to making "closed" formularies the default choice.[17] For example, while health plans traditionally had to opt into closed formularies, in 2014, Express Scripts's national formulary was a closed formulary, and clients had to affirmatively opt-out of it.[18]

63. Over the last several years, the Defendant PBMs have published annual lists of drug exclusions. PBMs' exclusion lists are closely analyzed by industry experts who understand that, through these lists, PBMs have the ability to drive health and insurance plan participants and beneficiaries to (or away from) specific drugs.[19] For example, in an August 2, 2016 article about CVS Caremark's and

[17] Thomas Reinke, *PBMs Just Say No to Some Drugs — But Not to Others*, Managed Care Mag. (Apr. 5, 2015), https://www.managedcaremag.com/archives/2015/4/pbms-just-say-no-some-drugs-not-others.

[18] *Id.*

[19] *See, e.g.*, Kevin McCaffrey, *PBMs Unveil 2017 Formularies, Retain Focus on Exclusions*, MM&M (Aug. 2, 2016), https://www.mmm-online.com/payersmanaged-markets/pbms-unveil-2017-formularies-retain-focus-on-exclusions/article/513737/; Mark Lowery, *2016 Formulary Exclusions in 9 Key Areas*, Drug Topics: Voice of the Pharmacist (Aug. 11, 2015), http://drugtopics.modernmedicine.com/drug-topics/news/2016-formulary-

Express Scripts's 2017 formulary exclusions, *Barrons* stated:

> Make way for some waves. CVS Health (CVS) and Express Scripts (ESRX) have released their formulary exclusion list for 2017, which details which prescription drugs will not be covered by health plans.
>
> Why do we care?...The coverage list determines whether millions of privately insured individuals can easily use an insurance co-payment to buy their prescriptions. If a drug is excluded, it can dramatically hobble sales.
>
> Thus, the formulary exclusion lists can be used as a tool by insurers and PBMs — leverage you might say — to negotiate with drug makers for better prices [for PBMs and plans].[20]

64. Formulary placement (and potential exclusion) is a major factor in the Defendant PBMs' negotiations with drug companies like the Defendant Drug Manufacturers for rebates and other types of payments. The PCMA (the PBM trade association) states that "[i]n classes where several products may be considered therapeutically equivalent, PBMs can negotiate with drug manufacturers for higher rebates[.]"[21] In April 2015, Express Scripts's Chief Medical Officer told *Managed*

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exclusions-9-key-areas; Bruce Japsen, *PBMs Quietly Gain Leverage As Drug Makers Stumble On Price Hikes*, Forbes (Aug. 31, 2016), https://www.forbes.com/sites/brucejapsen/2016/08/31/pbms-quietly-gain-leverage-as-drug-makers-stumble-on-price-hikes/#554d1a3f7ffa.

[20] Johanna Bennett, *CVS Health Takes "An Audacious Step" With 2017 Drug Formularies*, Barron's (Aug. 2, 2016), https://www.barrons.com/articles/cvs-health-takes-an-audacious-step-with-2017-drug-formularies-1470169569; *see also Excluded in 2016: These Drugs Are On the Outside Looking In*, Managed Care Mag. (Sept. 10, 2015), https://www.managedcaremag.com/archives/2015/9/excluded-2016-these-drugs-are-outside-looking.

[21] *Drug Price Negotiations & Rebates*, Pharm. Care Mgmt. Ass'n,

Care Magazine that formulary exclusions "demonstrate that PBMs [can] move market share."[22] He further touted that drug companies "[are] now convinced . . . that [PBMs can] actually deliver market share when we [are] motivated to. So we went to the companies, and we told them, 'We're going to be pitting you all against each other. Who is going to give us the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products.'"[23]

65. Similarly, a February 16, 2018 article in *STAT* (a well-known publication focused on the life sciences and pharmaceutical industries) states that PBMs — particularly the Defendant PBMs — "[a]s the industry's heavyweights . . . now have enormous power over the availability and pricing of essential medicines. Drug makers pay PBMs billions of dollars to ensure their products get preferred positions on formularies, drug lists used to determine which medicines are covered."[24] Industry experts have further highlighted that the threat of formulary

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https://www.pcmanet.org/policy-issues/drug-price-negotiations-rebates/.

[22] Peter Wehrwein, *A Conversation With Steve Miller, MD: Come in and Talk With Us, Pharma*, Managed Care Mag. (April 2015), *available at* https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma.

[23] *Id.*

[24] Casey Ross, *Washington Is Taking Aim at Drug Industry Middlemen. But Can It Break Their Grip on a Captive Market?*, STAT (Feb. 16, 2018), https://www.statnews.com/2018/02/16/washington-pharmacy-benefit-managers/.

exclusion has yielded substantial drug company payments to PBMs. In a presentation, Arthur Shinn of Pharmacy Consultants, LLC stated that "[t]he exclusion strategy is a big rebate revenue generator."[25]

c) PBMs' Control Over Their Own Compensation Through Rebate and Administrative Fees

66. Defendant PBMs generally pass through only *a portion* of specified "rebates" to client insurers and health plans.[26] Moreover, PBMs have written their contracts to retain for themselves all other payments from drug manufacturers like the Defendant Drug Manufacturers, including among other things discounts, "administrative or other fees," and/or side deals, and thus, the Defendant PBMs keep substantially more of the moneys received from drug makers than they pass through. The result is that the Defendant PBMs profit handsomely from rebates.[27]

67. In addition to rebates, drug companies like the Defendant Drug Manufacturers often pay Defendant PBMs substantial amounts of various "administrative fees" in exchange for, among other things, ensuring a given drug's

[25] "As the Clock Ticks for Exclusion Opt-Ins, Payers Ponder Access, Disruption, Savings", Drug Benefit News, Vol. 15, Issue.

[26] *It's Time To Determine How Much Your PBM Is Depriving Your Plan of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/.

[27] "How to Dramatically Decrease Your MCO's Rx Coverage Costs," Managed Care, April 1, 2008 https://www.managedcaremag.com/archives/2008/4/how-dramatically-decrease-your-mco-s-rx-coverage-costs.

formulary placement.[28] As Express Scripts states in its template contract with Flint, Michigan:

> ESI provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price, or (ii) 5.5% of the wholesale acquisition cost of the products. In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These service fees are not part of the formulary rebates or associated administrative fees.[29]

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[28] Henry C. Eickelberg, *The Prescription Drug Supply Chain "Black Box" — How it Works and Why You Should Care*, Am. Health Pol'y Inst. (2015), http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharma_Black_Box.pdf; *see also* Linda Cahn, *It's Time To Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition (NPCC), http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/.

[29] Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (February 27, 2015), available at http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf.

68. As industry expert, Linda Cahn observed "[i]f a PBM enters into contracts with drug manufacturers and chooses to give rebates another name — like administrative fees or health management fees or grants — the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients."[30] Additionally, "a PBM can deprive its clients of rebates by ensuring the rebates are paid on the basis that is not attributable to the clients' drug purchases."[31]

69. PhRMA, an industry group of pharmaceutical manufacturers, has explained:

> In addition to rebates, PBMs often *require* manufacturers to pay administrative service fees for administering, invoicing, and collecting rebate payments. These administrative fees are intended to reimburse the PBM for services provided to the manufacturer and are not generally passed on to the PBM's client.[32]

70. Altarum, a nonprofit research and consulting organization that works with governments and private insurers to improve health outcomes for Medicare and Medicaid beneficiaries, stated:

> The concern is that PBMs, in their role as intermediaries, have

[30] Linda Cahn, "Don't Get Trapped By PBM's Rebate Labeling Games" Managed Care (Jan. 1, 2009), *available at* https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games.

[31] *Id.*

[32] "Follow the Dollar," PhRMA (Nov. 2017), at 8, *available at* http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf (emphasis added).

> diverted much of the potential savings to their own bottom lines, a concern intensified by the lack of transparency around the proprietary rebate amounts. Examples include PBMs retaining more than their agreed upon share of rebates through re-labeling rebates as fees and PBMs pressuring manufacturers to increase their list prices with a commensurate increase in rebates. This benefits PBMs doubly since they are often paid a percentage of list price and also retain a share of rebates.[33]

71. For example, in a February 14, 2017 letter to HHS, regarding PBM practices, pharmaceutical company, Eli Lilly stated that:

> [There] is an emerging practice by some (but certainly not all) of these [PBM] entities to condition a manufacturer's ability to bid for federal government business on the willingness of manufacturer[s] to accept a non-negotiable suite of administrative services at a non-negotiable rate. From Lilly's perspective, this is in effect a "pay-to-play" requirement.[34]

Thus, according to Eli Lilly, drug manufacturers are paying administrative fees (which do not flow to the health plans to any significant extent) to PBMs in exchange for formulary placement.

72. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to Dross, the pharmacy-benefits consultant who has been cited in Senate testimony, administrative fees can

[33] Charles Roehrig, The Impact of Prescription Drug Rebates on Health Plans and Consumers, Altarum (Apr. 2018), at 4.

[34] Letter from Josh O'Harra, Assistant General Counsel for Eli Lilly, to Patrice Drew, Office of the Inspector General, February 14, 2017, *available at* https://www.regulations.gov/document?D=HHSIG-2017-0001-0002.

amount to 25-30% of total payments from drug companies like the Defendant Drug Manufacturers.[35] Similarly, Express Scripts revealed in a 2017 lawsuit that it filed against one drug manufacturer that it kept 13 times more in administrative fees than it passed back to its clients through "rebates."[36]

73. That the Defendant PBMs have, in fact, retained increasing amounts of rebates and fees for themselves is demonstrated by a March 2019 Pew Center study which analyzed manufacturer rebate levels, health-plan drug expenditures and PBM revenues from drug expenditures during the period 2012-2016.[37] That study found that even though manufacturers paid greater rebates during the period 2012-2016,[38] those rebates did not actually reduce health-plan expenditures on drugs — which

[35] David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business?*, Mercer (July 31, 2017), https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html.

[36] http://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/. According to Express Scripts's complaint, it entered into "rebate agreements" with the drug manufacturer, which required the manufacturer to pay Express Scripts far more in "administrative fees" than the manufacturer paid in "formulary rebates." The administrative fees were about 13 times the rebates.

[37] *The Prescription Drug Landscape Explored, A look at retail pharmaceutical spending from 2012 to 2016*, March 2019 Pew Center Report, *available at* https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.

[38] Manufacturer rebates increased from $10.2 billion in 2012 to $29.1 billion in 2016. *Id.* at 9.

increased by 66% from 2012-2016.[39] The report observed that as health plans were being forced to spend more and more on drugs, PBM revenues virtually doubled because they retained increased percentages of rebates for themselves and increasingly took their payments from manufacturers in the form of "fees" that they did not share with their health-plan clients.

74. The Pew Center report estimated that

- in 2012, PBMs retained $11.6 billion in rebates and fees related to drug expenditures (which was composed of $5.7 billion in manufacturer rebates and $5.9 billion in manufacturer fees), which constituted 4.6% of total Prescription Drug spending.

- by 2015 (3 years later), PBMs retained $18.2 billion in rebates and fees related to drug expenditures (which was composed of $7.8 billion in manufacturer rebates and $10.4 billion in manufacturer fees), which constituted 5.6% of total Prescription Drug spending.

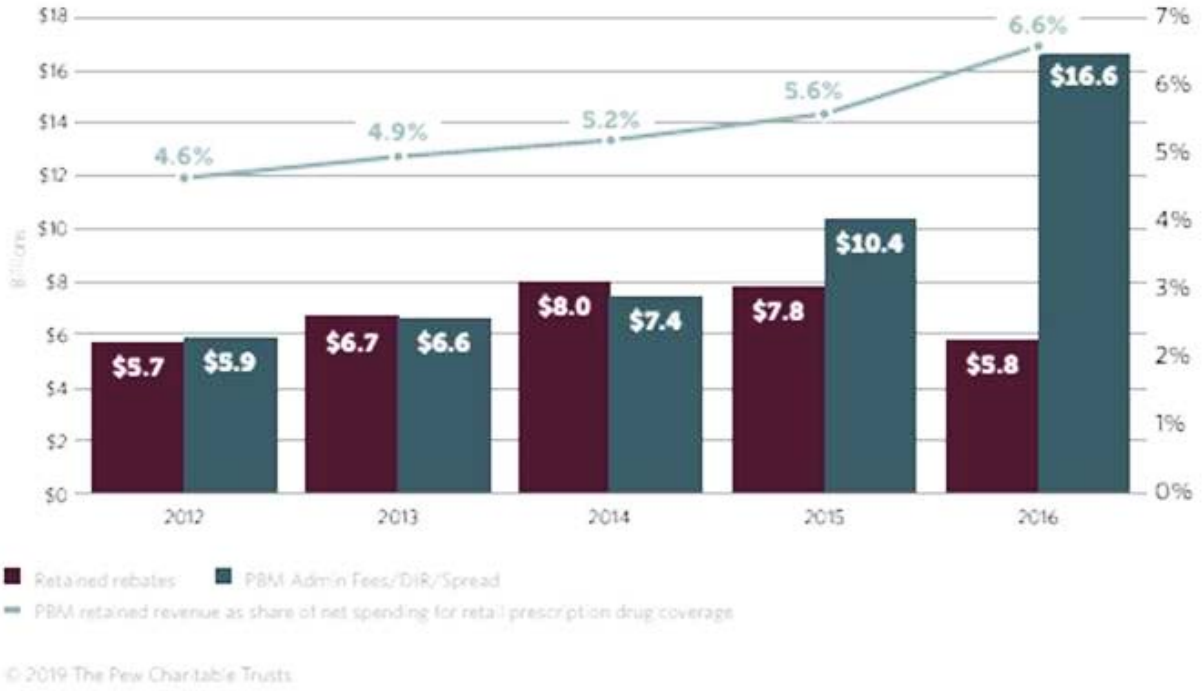
- by 2016 (4 years later), PBMs retained $22.4 billion in rebates and fees related to drug expenditures (which was composed of $5.8 billion in manufacturer rebates and $16.6 billion in manufacturer fees), which constituted 6.6% of total Prescription Drug spending.[40]

[39] In 2012, $110.6 billion in commercial health plan premiums went to pay for retail prescription drugs, and by 2016 $183.9 billion of commercial health plan premiums went to pay for retail prescription drugs — a 66% increase in drug expenditures over a four-year period. *Id.* at 8.

[40] *Id.* at 13.

Figure 9

PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16



Thus, over a four-year period, while health-plans and consumers were forced to spend more on drug expenditures because of surging drug prices, PBM revenues virtually doubled (from $11.6 billion to $22.4 billion) because PBMs retained more and more manufacturer rebates, and service fees (which are not shared with health plan clients) virtually tripled. Notably, PBM-retained rebates and fees increased not only in total dollar terms, but also as an increasing percentage of total drug expenditures. Thus, at a time when while health plans and consumers were forced to spend more on drug expenditures because of surging drug prices, PBMs, including Defendant PBMs, were increasing the percentage of drug expenditures they kept for

themselves.

75. Thus, while Defendant PBMs pass some rebates and fees back to the plans, they also retain a large portion of such moneys, in part through misleading labeling of the various rebates and fees they receive from drug companies like the Defendant Drug Manufacturers. This lack of transparency, and the Defendant PBMs' central role in ensuring it, gives the PBMs authority and discretion to label the payments that they negotiate with the Defendant Drug Manufacturers such that they retain control over the amount of kickbacks they keep for themselves. Thus, the hard bargains Defendant PBMs purport to drive for their clients — the plans or their participants and beneficiaries — are, in reality, for the Defendant PBMs themselves.

B. LIST PRICE INCREASES WERE USED TO GENERATE BRIBE MONEY AND PASS THE COST OF THE BRIBES TO DIRECT PURCHASERS

76. As alleged above, historically, PBMs that acted in their health-plan client's interests used their formulary power to favor lower-priced drugs in order to force down drug list prices (or slow the growth of list prices). However, during the last decade the Defendant PBMs have been bribed to eliminate the price-disciplining effects from competition. Because so much of the rebates and fees flow into the Defendant PBMs' coffers (rather than being paid to their clients), the Defendant PBMs benefit from higher WAC prices because it results in higher rebate and fee

payments that they keep for themselves (even though doing so is contrary to the interests of the PBMs' health-plan clients).

77. The rebates and administrative fees that the Defendant PBMs receive for a drug are usually calculated as a percentage of the dollar value of a drug's usage based on its WAC list price — such as 30% of a drug's total unit volume purchases by the PBM's clients multiplied by the WAC list price per unit. The total amount of a drug's purchases (and thus the total amount of the rebates and fees paid to a PBM for that drug) are driven by two factors: a drug's list price (WAC or AWP, which is typically WAC plus 20%), and its sales volume. For example, the total purchase amount for 1000 units of a $300 drug is $300,000, and the total purchase amount for 1000 units of a $100 drug is $100,000. If a PBM receives a 30% rebate for both drugs, then the PBM receives $90,000 in rebates for the $300 drug, and $30,000 for the $100 drug. In that context, it is in the PBM's interest to drive sales to the higher-priced $300 drug, even though that is contrary to the financial interests of its health-plan clients who pay the higher prices but do not receive many of the accompanying rebates and fees that are kept by the PBM.

78. Furthermore, the Defendant PBMs benefit from large, annual list price increases by drug manufacturers that occur during the life of a multi-year contract for two reasons. First, increases in a drug's list price increase the dollar-amount of the rebate and fee payments that the PBMs get to keep. For example, if a PBM

receives a 30% rebate on 1000-unit sales of a $300 drug, if the drug price increases by $100 per unit, then the PBM's rebates increase by $30,000 (from $90,000 to $120,000).

79. In addition, large drug price increases during a multi-year contract can generate additional fees and rebates to PBMs in the form of "price-protection" benefits that Defendant PBMs do not share with their health plan clients. A recent report on the drug industry noted that, in addition to rebates used to purchase formulary access and market share, price/inflation protection rebates also incentivize drug manufacturers to raise list prices and thereby compensate Defendant PBMs for formulary placement:

> At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher list price increases than would otherwise occur[.] . . . Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers' [list price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid list price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of list price inflation at least as high, and ideally just a bit higher, than peers'. Durable list price inflation is the natural result.[41]

[41] Richard Evans, Scott Hinds, & Ryan Baum, US Rx Net Pricing Trends Thru 2Q16, SSR LLC, 36 (Oct. 5, 2016).

As OptumRx's CEO candidly admitted in an October 15, 2016 interview with *Modern Healthcare*, "the largest players" in the PBM industry — the Defendant PBMs — "actually benefit from price increases."[42]

80. This has created a perverse incentive for: (a) the Defendant PBMs to give preferential formulary status to higher-priced drugs which come with higher payments to the PBMs, even if doing so is contrary to the health plan clients' interest in favoring lower-priced drugs; and (b) for drug manufacturers such as the Defendant Drug Manufacturers to use high rebate and fee payments to purchase favorable formulary status from Defendant PBMs, instead of trying to ensure favorable formulary status by lowering list prices or limiting list price increases.

81. The Defendant PBMs' interest and benefit in favoring high-priced drugs and large price increases (contrary to their clients' interests) makes them ripe targets to be bribed by brand manufacturers such as the Defendant Drug Manufacturers who pay kickbacks (*i.e.*, rebates that flow into the Defendant PBMs' coffers and not to the health-plan clients) to gain the ability to raise list prices without being penalized by the PBMs. In a March 7, 2018 speech to America's Health Insurance Plans' ("AHIP") National Health Policy Conference, FDA Commissioner Scott Gottlieb discussed how the PBMs have "misaligned incentives" which cause

[42] *Q&A: We Don't Set the Price. Pharmaceutical Manufacturers Set the Price*, Mod. Healthcare (Oct. 15, 2016), *available at* http://www.modernhealthcare.com/article/20161015/MAGAZINE/310159957.

them to "use their individual market power to effectively split some of the monopoly rents with large manufacturers and other intermediaries rather than passing on the saving garnered from competition to patients and employers."[43] In essence, rather than using their control over day-to-day formulary decisions to penalize manufacturers who charge excessive prices, PBMs can be bribed with a share of excessive, supra-competitive prices that flow into their pockets to look the other way while brand manufacturers (such as the Defendant Drug Manufacturers) raise list prices.

82. In fact, PBMs actually work to discourage price reductions. As the drug-makers' trade association, PhRMA, has stated:

> Under the current system, the revenues PBMs earn on medicines could decline if the prices of medicines were to decrease. . . . **[A] hypothetical manufacturer's unilateral decision to lower list price could result in a PBM then taking action to significantly reduce formulary access for that manufacturer's medicine**.
>
> * * *
>
> Similarly, OIG has observed that "[t]he prominence of rebate arrangements in the prescription drug supply chain has been cited as a potential barrier to lowering drug costs" and that under the current system, **PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred formulary tier**. **Information published by industry analysts shows that similar penalties may exist if manufacturers attempt to lower list prices without modifying**

[43] Scott Gottlieb, M.D., Capturing the Benefits of Competition for Patients (March 7, 2018), *available at* https://www.fda.gov/news-events/speeches-fda-officials/capturing-benefits-competition-patients-03072018.

> **their contract terms to provide a corresponding increase in the rebates received by the PBM**.[44]

Analysts have also observed that PBMs' earnings would "take a direct hit if drug companies began to slow down on price hikes."[45]

83. Indeed, Defendant PBMs have implemented policies that penalize drug makers who lower their list prices. These policies are concrete evidence that in order to share in the excessive, supra-competitive prices, Defendant PBMs have acted contrary to their health plan clients' interests, in derogation of their duty of fidelity and/or fiduciary duty. Almost half of those surveyed by the National Pharmaceutical Council expressed the view that rebates contributed to misaligned incentives that put Defendant PBMs' business interests before those of their clients or patients.[46]

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[44] Letter from PhRMA, to Daniel R. Levinson, Office of the Inspector General, April 8, 2019, at 15-16 (emphasis added) (citing Carolyn Y. Johnson, "In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet." THE WASHINGTON POST (June 26, 2018) (pharmaceutical manufacturers "argue that PBMs that make their money off negotiating rebates may prefer a competing drug with a higher list price and a bigger rebate.")); Max Nisen, "Pharma's Quieter Price War Continues," BLOOMBERG BUSINESSWEEK (Aug. 3, 2007).

[45] Linette Lopez, "These companies you've never heard of are about to incite another massive drug price outrage," BUSINESS INSIDER (Sep. 12, 2016), *available at* https://www.businessinsider.com/scrutiny-express-scripts-pbms-drug-price-fury-2016-9.

[46] National Pharmaceutical Council, Toward Better Value: Employer Perspectives on What's Wrong With the Management of Prescription Drug Benefits and How to Fix It (Oct. 2017), *available at* http://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf.

84. The problem has grown so significant that in February 2019 HHS proposed a rule to change how PBMs are compensated. Although the proposed rule was ultimately withdrawn, the commentary from the Secretary of Health and Human Services and the Inspector General was not, and remains accurate and relevant. The Federal Register notice for comment stated, *inter alia*, as follows:

> The prominence of rebate arrangements in the prescription drug supply chain has been cited as a potential barrier to lowering drug costs. For instance, **the system may create incentives for manufacturers to raise list prices and discourage manufacturers from reducing their list prices or, in some cases, penalize them if they do**.
>
> Often, a portion of PBM compensation is derived from the savings they create, or the gap between the list price and "net price." This compensation may be derived from retaining a portion of the rebate, as well as receiving "price protection" payments from manufacturers. Rebates and price protection payments increase when list prices increase. Thus, there may be a greater incentive for a PBM to encourage the use of drugs with higher list prices, typically via preferred formulary placement, than the use of lower price drugs that would generate lower rebates or price protection payments. **A manufacturer choosing to lower the list price of a drug would be reducing the gap between list price and "net" price, which would reduce either the size of the rebate or price protection guarantee. This could result in a drug being removed from the formulary or being placed in a less-preferred formulary tier**. As a result, the current system works to the disadvantage of beneficiaries, and the Federal health care programs.[47]

[47] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefits Manager Service Fees, A Proposed Rule by the Health and Human Services Department, 84 Fed. Reg. 2340 (Feb. 6, 2019) (emphasis

85. The Secretary of Health and Human Service's and Inspector General's observations have been echoed and confirmed by various entities throughout the health-care industry. For example, the Alliance for Transparent and Affordable Prescriptions (which represents various patient and provider groups[48]) stated in comments to the Proposed Rule that:

> [O]ur current system is such that the patient is encouraged to use the product that provides the most rebate potential to the PBM. Throughout the proposed rule, OIG highlights that the current rebate structure may actually result in PBMs placing more expensive products in a preferred formulary position over less expensive equivalents. This is because a more expensive product generates a higher rebate. This system benefits no one but the PBM.
>
> The current rebate system encourages pharmaceutical manufacturers to set high list prices, as these prices are just the starting point of negotiations with the PBM. OIG notes that this

added), *available at* https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

[48] American Association of Clinical Urologists, American College of Rheumatology, Association of Women in Rheumatology, California Rheumatology Alliance, Coalition of State Rheumatology Organizations, Florida Society of Rheumatology, Global Healthy Living Foundation, International Foundation for Autoimmune & Autoinflammatory Arthritis, Lupus and Allied Diseases Association, Inc., National Infusion Center Association, National Organization of Rheumatology Managers, New York State Rheumatology Society, North Carolina Rheumatology Association, Ohio Association of Rheumatology, Rheumatology Alliance of Louisiana, Rheumatology Nurses Society, South Carolina Rheumatism Society, Tennessee Rheumatology Society, and U.S. Pain Foundation.

system is a "potential barrier to lowering drug costs."

* * *

> If net prices are flat or even declining, why do patients have more trouble than ever affording the medicines they need? The answer is that little of these savings make it to patients, because the "savings" are absorbed by the middlemen as revenue. Rebates are not savings for patients; they are income for PBMs.[49]

86. Likewise, Navitus Health Solutions, a 100% pass-through PBM[50] stated in comments to the HHS Proposed Rule that:

> [T]raditional PBM business models may drive up drug expenses by promoting higher cost agents in their quest to secure higher rebates from drug manufacturers because traditional PBMs often keep a portion of the rebates that they negotiate.
>
> [R]ebates from drug manufacturers warp the incentives that PBMs are operating under, creating a market dysfunction where the goals of CMS and the Part D plans are not aligned with those of the PBMs providing services to the plans. For PBMs, the amount of rebates that are paid to Part D plans are often used as a rough measure of performance by the plans and their consultants in the process of PBM service acquisition and ongoing PBM services. However, higher rebates are not

[49] Letter from Alliance for Transparent & Affordable Prescriptions to OIG (Apr. 2, 2019) at 2-3, *available at* https://static1.squarespace.com/static/593e9cb8db29d6d8538e36a1/t/5ca3d2b8c8302522a6585dae/1554240185296/ATAP+--+Rebate+Rule+Letter+2019.pdf.

[50] Unlike most PBMs, Navitus "pass[es]-through to [its] clients all of the payments that [it] receives from drug manufacturers in the form of rebates, incentives, administrative fees, data fees, and any other amounts that [it] receives from drug manufacturers." Testimony of Brent Eberle, R.Ph, MBA, Chief Pharmacy Officer, Navitus Health Solutions, to the U.S. House of Representatives, Energy and Commerce Committee Subcommittee on Health on May 9, 2019, at 1, *available at* https://docs.house.gov/meetings/IF/IF14/20190509/109436/HHRG-116-IF14-Wstate-EberleB-20190509.pdf.

> necessarily a good proxy for lower costs. … When PBMs choose drugs with higher rebates but higher costs over comparable drugs with lower overall costs, then the total costs can be significantly higher for the plans and CMS in spite of the higher rebates.
>
> * * *
>
> If drug manufacturers are paying PBMs money that the PBMs keep, then the PBMs have an incentive that is not consistent with goals of lowering prices and overall costs. **Instead, PBMs would have the incentive to keep manufacturers happy in order to continue receiving such payments from manufacturers. Manufacturers have the goal of increasing overall revenue**, which normally means keeping their drugs on each formulary in a preferred status to increase sale volume for their drugs at the highest prices possible. **Allowing drug manufacturers to continue to pay PBMs will allow the manufacturers to influence PBM decisions, implicitly or explicitly, including decisions to keep overpriced drugs on the formularies and continually enabling escalating drug prices**. Regardless of what payments from manufacturers are labeled, they all impact PBMs' incentives unless they are fully passed through to the plans, Part D beneficiaries, or CMS and used to reduce overall drug prices.[51]

87. Similarly, a February 2018 white paper issued by the White House Counsel of Economic Advisors states that, through the negotiation of secret rebates, PBMs generate enormous profits for themselves while at the same time inducing drug companies to increase their list prices:

> [T]he PBM market is highly concentrated. Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and

[51] Letter from Paul M. Page, General Counsel of Navitus Health Solutions to Aaron Zajic, Office of Inspector General, Department of Health and Human Services (April 5, 2019) at 1, 3 (emphasis added).

> against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves. Over 20 percent of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system. The size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret. The system encourages manufacturers to set artificially high list prices[.][52]

88. Defendant Drug Manufacturers' executives have readily admitted that the price increases are directly tied to — and the result of — the bribes and kickbacks to Defendant PBMs. For example, an October 2016 *Wall Street Journal* article reported that Enrique Conterno (president of Defendant Lilly's diabetes business) stated that:

> The reason drugmakers sharply raise list prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists.[53]

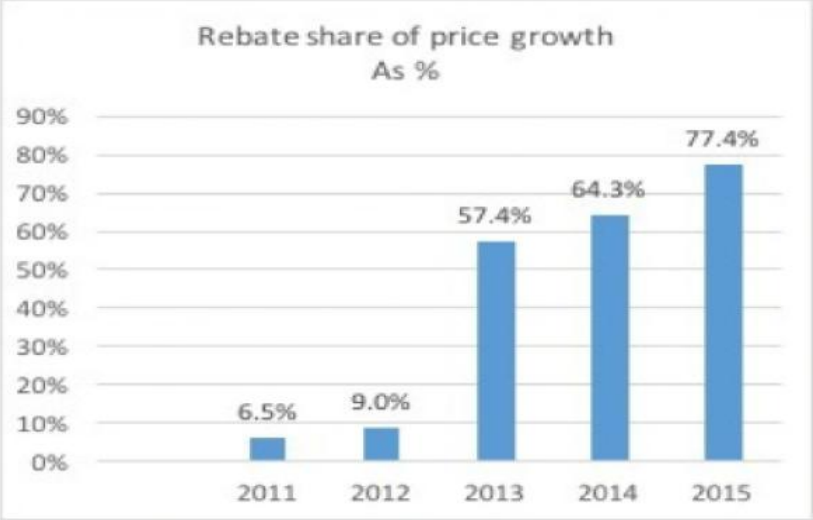
89. Similarly, Defendant Novo Nordisk stated in a 2016 open letter that "as the rebates, discounts and price concessions got steeper, we were losing considerable revenue …. So, we would continue to increase the list [price] in an attempt to offset the increased rebates, discounts and price concessions to maintain a profitable and

[52] *Reforming Biopharmaceutical Pricing at Home and Abroad*, White House Counsel of Econ. Advisors (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (citations omitted).

[53] Denise Roland and Peter Loftus, "Insulin Prices Soar While Drugmakers' Share Stays Flat," The Wall Street Journal (Oct. 7, 2016).

sustainable business."[54]

90. As a result of this scheme, drug manufacturer payments to Defendant PBMs for favorable formulary placement now account for the vast majority of drug list price increases over the last several years. A study conducted by the non-profit, non-partisan Center for Medicine in the Public Interest estimates that, from 2011-2015, rebates paid to PBMs grew as a percentage of total manufacturer list price increases from 6.5% to an astounding 77.4%. In 2016, these rebates accounted for 79% of total manufacturer list price increases.[55]



91. As Defendant PBMs have negotiated larger and larger rebates from

[54] Jakob Riis, President, Novo Nordisk Inc., "Perspectives from NNI President Jakob Riis on pricing and affordability" (Nov. 30, 2016).

[55] *See* Robert Goldberg, Ph.D., *Reduce Drug Prices by Cutting Out PBM Rebates*, DrugWonks.com (Apr. 15, 2016); Robert Goldberg, Ph.D., *Most of the Increase in Drug Spending Pocketed By PBMs and Insurers: What the Media Missed in Covering the IMS Drug Cost Study*, DrugWonks.com (Apr. 15, 2016), *available at* http://drugwonks.com/blog/most-of-the-increase-in-drug-spending-pocketed-by-pbms-and-insurers.

drug companies over the last several years — and drug prices have risen — Defendant PBM revenues have soared.[56]

92. Besides funding illegal bribes and kickbacks to Defendant PBMs, the list price increases also deliver increased revenues and profits to the Defendant Drug Manufacturers. For example, a data analysis discussed in a June 29, 2016 Bloomberg news article indicates that over a 6-year period (from Q42009-Q42015), Lilly raised the list price for Humulin R-U by 442%, and that 75% of the price increase was kept by Lilly, with 25% paid in rebates.

93. Defendant Drug Manufacturers have thus used list price increases not just as bribes and kickbacks to eliminate the Defendant PBMs' gate-keeping efforts, but also to benefit themselves from list price inflation.

[56] CVS Caremark's Pharmacy Services Segment saw revenues climb from $76 billion in 2013 to more than $120 billion in 2016. Between 2010 and 2016, Express Scripts's revenue jumped from approximately $45 billion to north of $100 billion. OptumRx's revenue increased from roughly $32 billion in 2014 to more than $60 billion in 2016. And Prime Therapeutics's revenues rose from $1.8 billion in 2012 to $4.73 billion in 2016. As of December 31, 2017, Express Scripts reported annual drug company payments of $2.58 billion, representing approximately 37% of its total net receivables. According to Professor Ed Ketz of Penn State, given the significant percentage of total net receivables from drug companies, "we can start thinking of the pharmaceutical companies as customers. They're not just bystanders in this equation." Linette Lopez, "The Feds just asked a huge healthcare company who their real clients are and the answer is totally unsatisfying," Business Insider US (Dec. 7, 2017), *available at* http://www.businessinsider.com/sec-looks-into-express-scripts-rebates-from-pharmaceutical-firms-2017-12.

C. DEFENDANT DRUG MANUFACTURERS' ILLLEGAL BRIBES AND KICKBACKS TO DEFENDANT PBMS VIA LIST PRICE INCREASES

1. Insulin Products

94. Diabetes is an epidemic in the United States. Diabetes occurs when a person has too much glucose — sugar — in her blood stream. Normally, the human body breaks down ingested food into glucose, which in turn feeds cells and enables them to function. In this process, insulin functions as a key, opening the cells and permitting glucose to enter. A lack of insulin or responsiveness to insulin causes the process to break down. Glucose is unable to enter the cells, which leads to high blood sugar levels. Unchecked, high blood sugar levels in a non-diabetic can lead to type 2 diabetes.

95. There are two basic types of diabetes. Roughly 90-95% of Americans living with diabetes developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce. When first diagnosed, many patients can initially be treated with tablets that help their bodies either secrete more insulin or better respond to the insulin they already produce. Nonetheless, these tablets are often insufficient for patients in the long term. To adequately control their blood sugar levels, many patients must inject insulin to supplement that which their bodies produce. About a quarter of type 2 patients rely on insulin treatment.

96. Type 1 diabetes occurs when a patient completely ceases insulin production. This form of diabetes is usually diagnosed in children and young adults, but can occur at any age. In contrast to type 2 patients, people with type 1 diabetes do not produce any insulin and, without regular injections of insulin, they will die. Individuals living with type 1 must rely on insulin treatments from the point of diagnosis until death.

97. One in five health care dollars is spent caring for people with diagnosed diabetes. Over 30 million people, 9.4% of the country, live with diabetes. A life-threatening disease, many of those living with diabetes rely on daily insulin treatments to survive. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days. Diabetic ketoacidosis is responsible for more than 500,000 hospital days per year at an estimated annual direct medical expense and indirect cost of $2.4 billion.[57]

98. Since insulin's discovery in 1922, Defendant Drug Manufacturers have developed a series of different Insulin products. Table 1 summarizes the current insulin treatment landscape.

Table 1: Insulin Available in the United States

Insulin Type	***Action***	***Brand Name***	***Generic Name***	***Company***	***FDA Approval***	***Benchmark Price (AWP)***

[57] Abbas E. Kitabchi, et al., *Hyperglycemic Crises in Adult Patients with Diabetes*, 32 Diabetes Care 1335, 1335 (2009).

Human	**Rapid-acting**	Humulin R	Insulin Regular	Eli Lilly	1982	$185.88 (vial[i])
		Novolin R	Insulin Regular	Novo Nordisk	1991	$172.13 (vial[ii])
	Intermediate	Humulin N	Insulin Suspension Isophane (NPH)	Eli Lilly	1982	$185.88 (vial[iii])
		Novolin N	Insulin Suspension Isophane (NPH)	Novo Nordisk	1991	$172.13 (vial[iv])
Analogs	**Rapid-Acting**	Humalog	Lispro	Eli Lilly	1996	$663.00 (pen[v]) $343.38 (vial[vi])
		Novolog	Aspart	Novo Nordisk	2000	$698.54 (pen[vii]) $361.70 (vial[viii])
		Apidra	Glulisine	Sanofi	2004	$651.76 (pen[ix]) $337.39 (vial[x])
		Fiasp	Aspart	Novo Nordisk	2017	$698.54 (pen[xi]) $361.70 (vial[xii])
	Long-Acting	Lantus	Glargine	Sanofi	2000	$505.36 (pen[xiii]) $336.93 (vial[xiv])
		Levemir	Detemir	Novo Nordisk	2005	$504.38 (FlexTouch[xv]) $367.19 (vial[xvi])
		Basaglar	Glargine	Eli Lilly	2016	$407.95
		Toujeo	Glargine	Sanofi	2015	$775.71(pen[xviii]
		Tresiba	Insulin Degludec	Novo Nordisk	2016	$745.53 (pen[xix])

[i] Novolin R 100units/ml Solution for Injection (vial, 10 ml Insulin Regular (Recomb) 100U/1mL, Solution for injection).

[ii] Novolin R 100units/ml Solution for Injection (vial, 10 ml Insulin Regular (Recomb) 100U/1mL, Solution for injection).

[iii] Humulin N 100unit/ml Suspension for Injection (vial, 10 ml Insulin Susp Isophane (NPH) (Recomb) 100U/1mL, Suspension for injection).

[iv] Novolin N 100units/ml Suspension for Injection (vial, 10 ml Insulin Susp Isophane (NPH) (Recomb) 100U/1mL, Suspension for injection).

[v] Humalog KwikPen 100unit/ml Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Lispro 100U/1mL, Solution for injection) (2017).

[vi] Humalog 100unit/ml Cartridge Solution for Injection (box, 5 cartridges, 3 ml Insulin Lispro 100U/1mL, Solution for injection) (2017).

[vii] Novolog FlexPen Prefilled Syringe 100unit/ml Solution for Injection (box, 5 pre-filled syringes, 3 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[viii] Novolog 100unit/ml Solution for Injection (vial, 10 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[ix] Apidra SoloStar 100units/ml Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Glulisine 100U/1mL, Solution for injection) (2018).

[x] Apidra 100unit/ml Solution for Injection (vial, 10 ml Insulin Glulisine 100U/1mL, Solution for injection) (2018).

[xi] Fiasp FlexPen Prefilled Syringe 100unit/ml Solution for Injection (box, 5 pre-filled syringes, 3 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[xii] Fiasp 100unit/ml Solution for Injection (vial, 10 ml Insulin Aspart (Recomb) 100U/1mL, Solution for injection) (2018).

[xiii] Lantus SoloStar 100units/ml Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Glargine 100U/1mL, Solution for injection) (2018).

[xiv] Lantus 100units/mL Solution for Injection (vial, 10 ml Insulin Glargine 100U/1mL, Solution for injection) (2018).

[xv] Levemir FlexTouch 100units/ml Solution for Injection (box, 5 pre-filled syringes, 3 ml Insulin Detemir (Recombinant) 100U/1mL, Solution for injection) (2016).

[xvi] Levemir 100units/ml Solution for Injection (vial, 10 ml Insulin Detemir (Recombinant) 100U/1mL, Solution for injection) (2018).

[xvii] Basaglar KwikPen 100units/mL Pre-Filled Pen Solution for Injection (box, 5 pens, 3 ml Insulin Glargine 100U/1mL, Solution for injection) (2017).

[xviii] Toujeo SoloStar 300units/mL Pre-Filled Pen Solution for Injection (box, 5 pens, 1.5 ml Insulin Glargine 300U/1mL, Solution for injection) (2018).

[xix] Tresiba Insulin Degludec 200units/mL Pre-Filled Pen Solution for Injection (box, 3 pens, 3 ml Insulin Glargine 200U/1mL, Solution for injection) (2018).

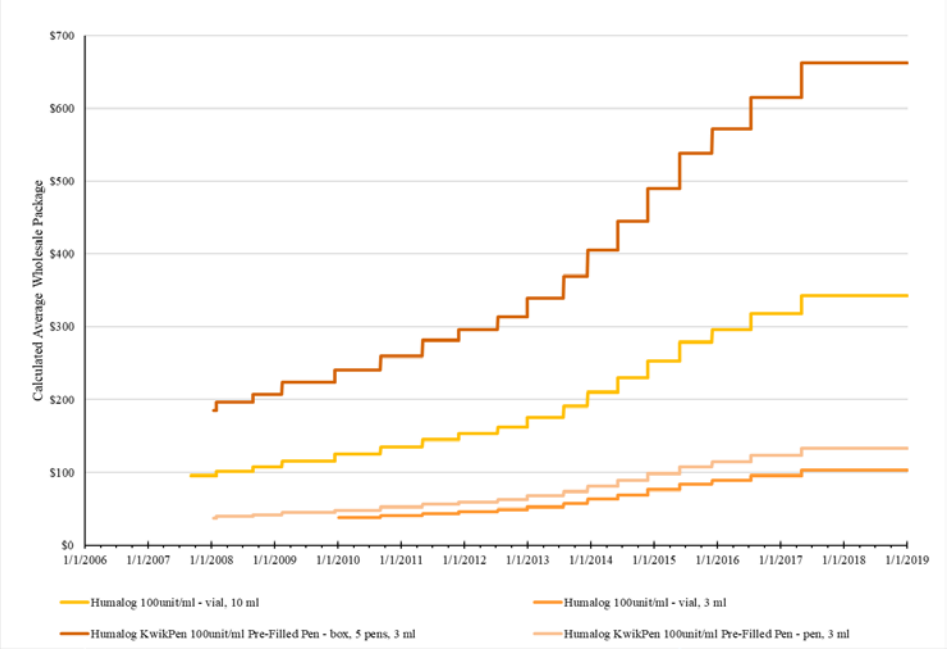
2. The Rapid Rise Of Insulin List Prices Starting in 2010

99. In the last five years alone, Eli Lilly, Novo Nordisk and Sanofi have

raised their list prices for Insulin as much as 300 to 900%. AWP prices that used to be $75 a decade ago are now between $300 and $700. And *nothing* about Defendant Drug Manufacturers' Insulins has changed in that period; the $700 drug is the exact same one the Defendant Drug Manufacturers sold for $75 years ago.

100. Figure 1 demonstrates Eli Lilly's price increases from 2006 to 2019 for Humalog.

Figure 1: Rising AWP prices of Humalog vials and pens from 2006-2019.



101. Figures 2 and 3 demonstrate Novo Nordisk's price increases from 2006 to 2019 for Levemir and Novolog.

Figure 2: Rising AWP prices of Levemir vials and pens from 2006-2019.

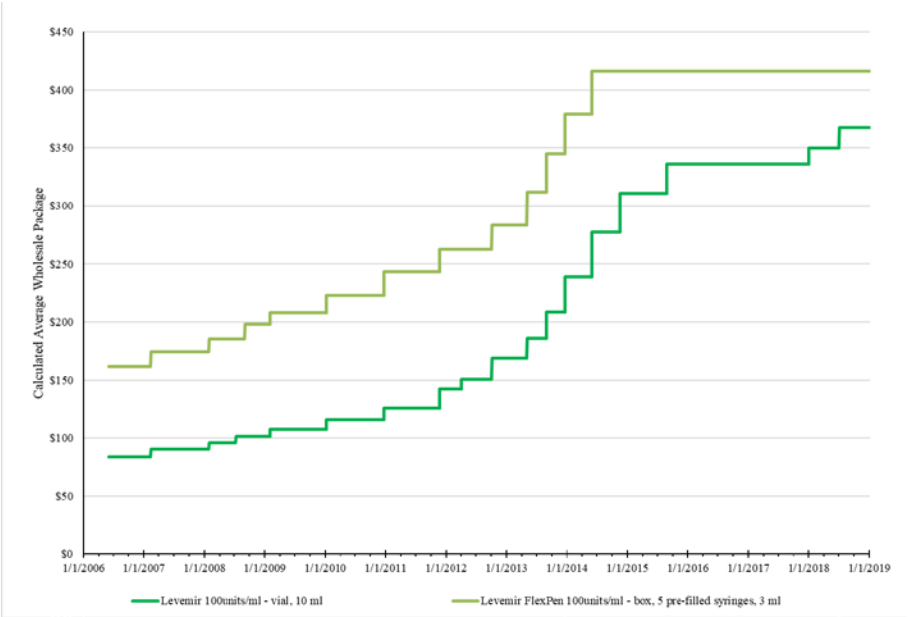
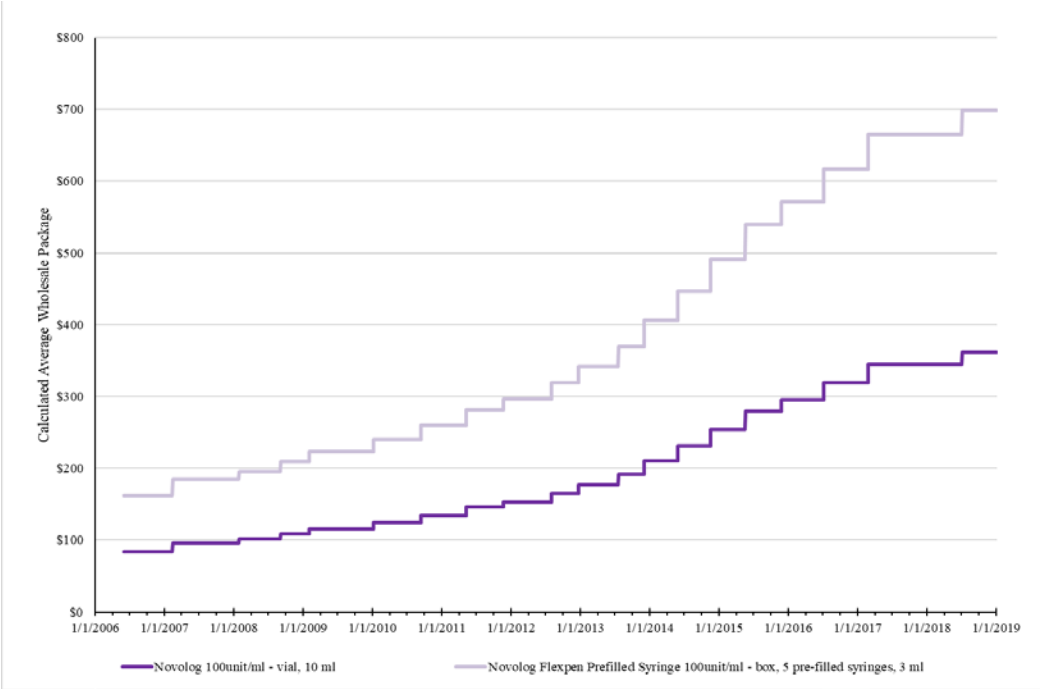


Figure 3: Rising AWP prices of Novolog vials and pens from 2006-2019.



102. Figures 4 and 5 demonstrate Sanofi's price increases from 2006 to 2019 for Lantus and Apidra vial and pen packages.

Figure 4: Rising AWP prices of Lantus vials and pens from 2006-2019.

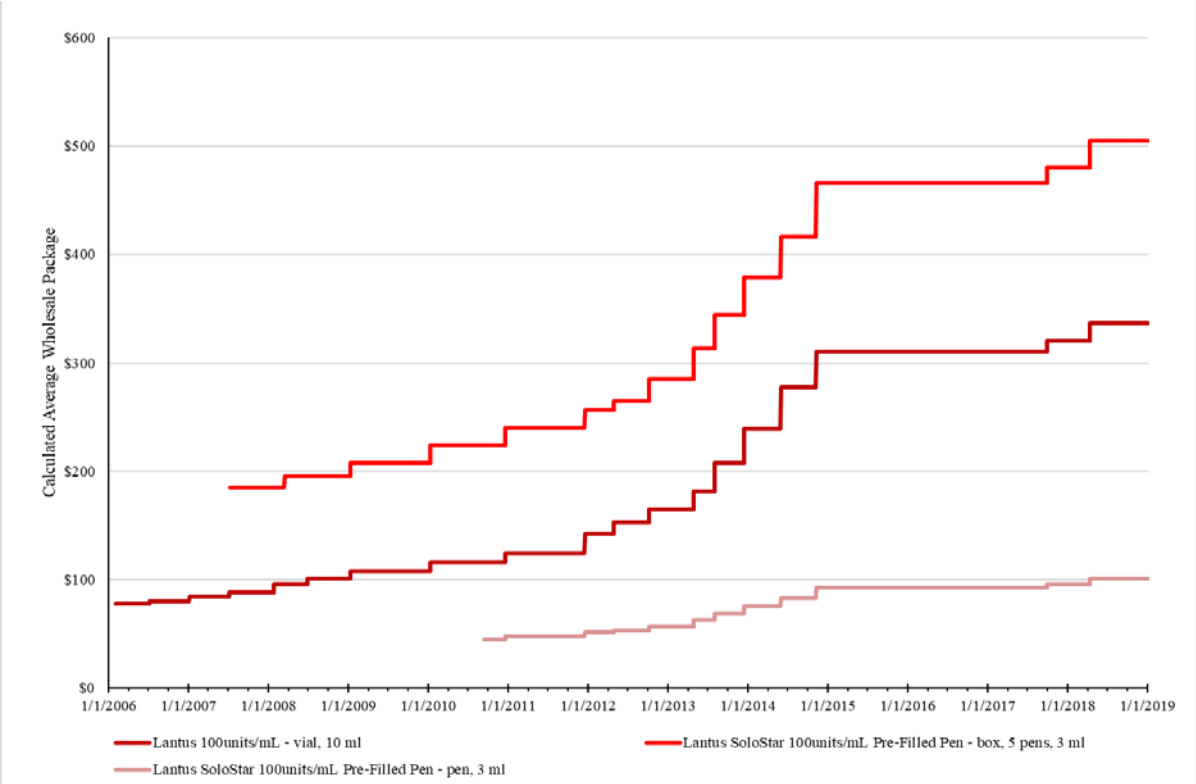
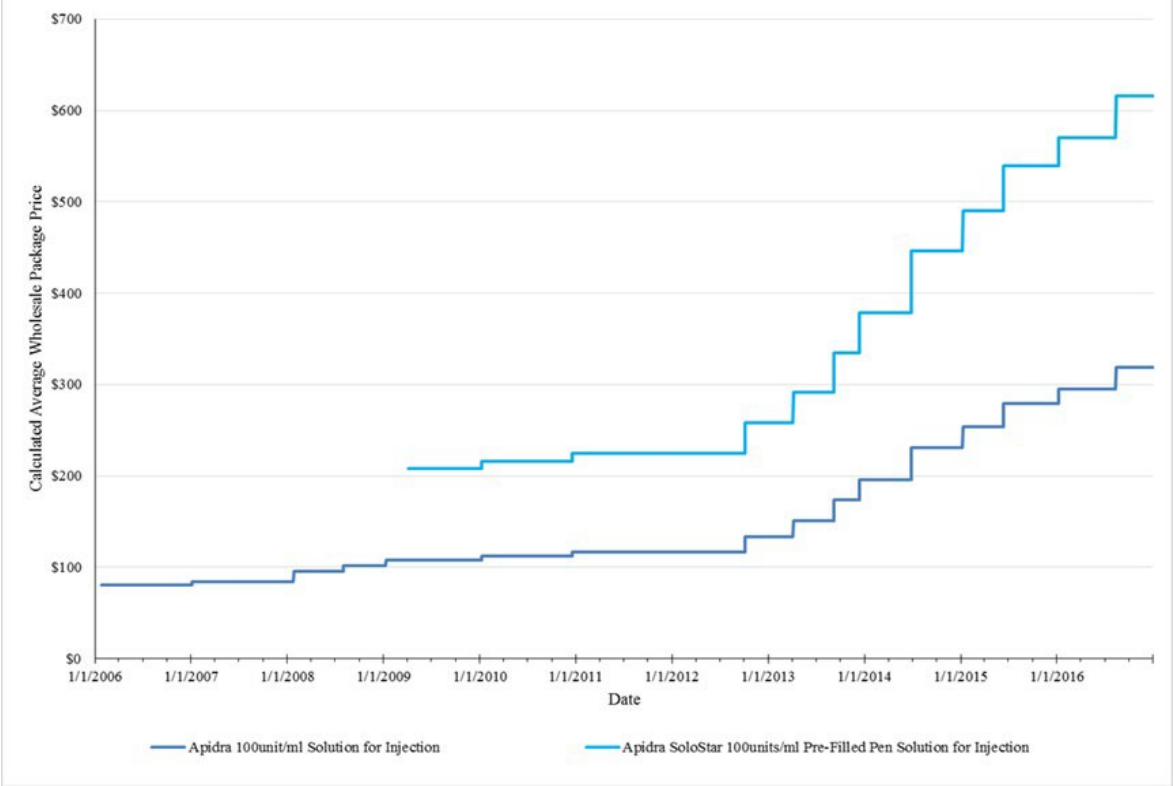


Figure 5: Rising AWP prices of Apidra vials and pens from 2006-2019.



103. The list prices of insulin analogs have not always been so high. In just the last five years, Sanofi and Novo Nordisk have raised Lantus's and Levemir's reported prices an astounding 168% and 169%, respectively. In 2016, Novo Nordisk and Sanofi were responsible for the highest drug AWP price increases in the entire pharmaceutical industry. This distinction largely reflected their price hikes for Lantus and Levemir, as shown in Figure 7. Figure 8 shows Novo Nordisk, Lilly, and Sanofi's exponential AWP price hikes from 2000 to 2015.

Figure 7: Rising Lantus and Levemir AWP prices from 2001-2015.

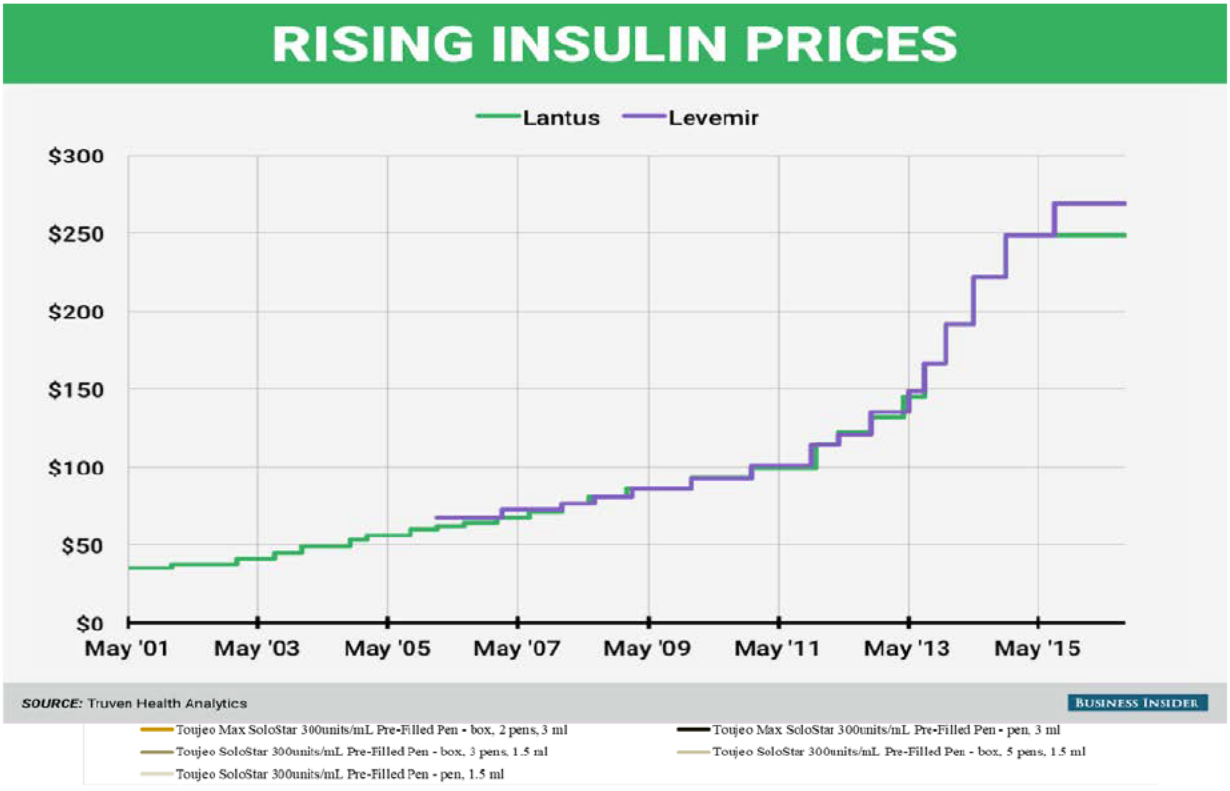
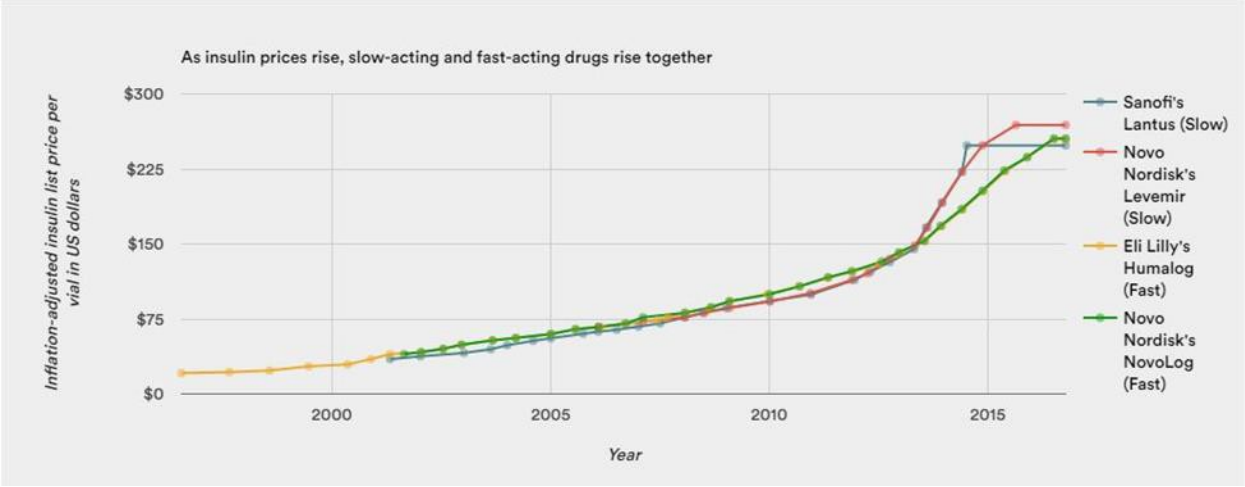


Figure 8: Rising insulin AWP prices from 2000-2015.[58]



104. In the past, Novo Nordisk maintained that its price increases reflected the "clinical benefit" of its drugs.[59] But Levemir and Novolog are the exact same drugs they were 10 years ago — the clinical benefits of these medicines have not changed. Where clinical benefit has not changed, it cannot be used to justify a 169% price increase.

105. The real reason Eli Lilly, Novo Nordisk and Sanofi have increased their list prices is to increase the pool of money that can be used to bribe Defendant PBMs, as described above.

106. On November 30, 2016, Novo Nordisk stated in a press release that it

[58] Rebecca Robbins, *The Insulin Market is Heading for a Shakeup. But Patients May Not Benefit*, STAT (Oct. 14, 2016), https://www.statnews.com/2016/10/14/insulin-prices-generics/.

[59] Allison Tsai, *The Rising Cost of Insulin*, Diabetes Forecast (Mar. 2016), http://www.diabetesforecast.org/2016/mar-apr/rising-costs-insulin.html.

"set[s] list price" with an eye to achieving "preferred" formulary status:

> We hear from more and more people living with diabetes about the challenges they face affording healthcare, including the medicines we make. . . . News reports on drug prices have left the public with an impression that companies like ours realize all the profits from the "list price" increases we've made over the last decade. In other words, a list price increase by XX percent leads to an automatic XX percent profit for the drug maker. We believe that is misleading and here's why: As the manufacturer, we do set the "list price" and have full accountability for those increases. However, after we set the list price, we negotiate with the companies that actually pay for the medicines, which we call payers. This is necessary in order for our medicines to stay on their preferred drug list or formulary. The price or profit we receive after rebates, fees and other price concessions we provide to the payer is the "net price." The net price more closely reflects our actual profits.[60]

107. Eli Lilly, too, has admitted that it raises AWP prices as a *quid pro quo* for formulary positions. An October 2016 *Wall Street Journal* article reported that Enrique Conterno (president of Lilly's diabetes business) stated that:

> The reason drugmakers sharply raise list prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists. [61]

108. Sanofi has also conceded its participation in this list price inflation

[60] Novo Nordisk Press Release (Nov. 30, 2016), *available at* http://press.novonordisk-us.com/leadership- perspectives?item=1.

[61] Denise Roland and Peter Loftus, "Insulin Prices Soar While Drugmakers' Share Stays Flat," The Wall Street Journal (Oct. 7, 2016).

scheme stating that: "since 2014, we have increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers in the US."[62]

V. FRAUDULENT CONCEALMENT AND TOLLING

A. LACK OF TRANSPARENCY IN DEFENDANT PBM CONTRACTS WITH DRUG COMPANIES CONCEALS THE DETAILS OF DEFENDANTS' BRIBERY AND KICKBACK CONDUCT

109. Because the insurers/health plans have no information about the Defendant PBMs' contract terms with the drug manufacturers,[63] Defendant PBMs are free to negotiate the payment of money by drug makers that falls outside the contract between the PBM and the insurer/health plan. As a result, Defendant PBMs secretly collect — and retain — large amounts of drug company payments simply by labeling those drug company payments differently than payments which the Defendant PBMs partly pass through to the insurers/plans. On information and belief, these payments transcend any particular plan, because they are based on total sales of a drug across the Defendant PBM's pool of plan clients. In short, contractual agreements often leave insurers/health plans with little idea what the PBM is actually being paid by drug manufacturers, and whether it is all being passed through to the

[62] Sanofi, Annual Report (Form 20-F) (Dec. 31, 2016).

[63] *It's Time To Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/.

insurer/health plan. Many payments from drug companies to PBMs are shrouded in secrecy and difficult to track.

110. In recent years, industry experts have confirmed this problem. For example, Linda Cahn of Pharmacy Benefit Consultants, a well-known PBM consultant to health plans, noted that PBMs routinely play a "Rebate Re-Labeling Game" in their client contracts. PBMs define drug company rebates in narrow terms in order to remit only a fraction of the amounts received from drug companies to their plan clients.[64] The Burchfield Group, a PBM auditing company based in Saint Paul, Minnesota, has echoed this concern.[65]

111. Likewise, the American Health Policy Institute has found that PBMs have responded to plan demands that PBMs pass back 100% of drug company payments by relabeling them:

> [T]he [PBM] industry has moved to 'reclassifying' the rebate dollars as 'purchase order discounts' or 'administrative fees.' Since the plan sponsor is often only contractually entitled to those things specifically defined in the contract as a 'rebate,' the PBM will pocket the purchase order discounts. Thus, while a

[64] Linda Cahn, "Don't Get Trapped By PBM's Rebate Labeling Games" Managed Care (Jan. 1, 2009), *available at* https://www.managedcaremag.com/archives/2009/1/ don-t-get-trapped-pbms-rebate-labeling-games.

[65] Chris Hanson-Ehlinger, *Receive full value from your PBM rebates*, Burchfield Group (Nov. 20 2014), http://www.burchfieldgroup.com/pharmacy-benefit-blog/bid/203233/Receive-full-value-from-your-PBM-rebates; Brett McCabe, *Getting Your Fair Share: 5 Tips for Optimizing PBM Rebates*, Burchfield Group (Apr. 26, 2017), http://www.burchfieldgroup.com/pharmacy-benefit-blog/getting-your-fair-share-5-tips-for-optimizing-pbm-rebates.

> plan sponsor may believe that it has negotiated a fully 'transparent' PBM deal (receiving 100 percent of the revenue coming from the manufacturer), what the plan sponsor doesn't realize is that some portion of the rebates have been carved-off and paid to the PBM as a purchase order discounts or admin fee, etc.[66]

112. HHS has remarked that PBMs hide from insurers/health plans the flow of money from drug manufacturers. In the February 2019 Federal Register notice for its proposed rule change, HHS wrote:

> 3. THE REBATE SYSTEM IS NOT TRANSPARENT
>
> In some or many instances, plan sponsors under Medicare Part D and Medicaid MCOs have limited information about the percentage of rebates passed on to them and the percentage retained by their PBMs. The terms of rebate agreements manufacturers negotiate with PBMs may be treated as highly proprietary and, in many instances, may be unavailable to the plans. For example, in a 2011 evaluation, OIG learned that some Part D plan sponsors had limited information about rebate contracts and rebated amounts negotiated by their PBMs.[67]

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[66] Henry C. Eickelberg, *The Prescription Drug Supply Chain "Black Box" — How it Works and Why You Should Care*, Am. Health Pol'y Inst. (2015), http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharma_Black_Box.pdf.

[67] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefits Manager Service Fees, A Proposed Rule by the Health and Human Services Department, 84 Fed. Reg. 2340 (Feb. 6, 2019), *available at* https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

Likewise, Congressman Earl Carter stated in a September 21, 2016 Congressional hearing that "Nobody knows how much of this is going to the pharmacy benefits manager, because there is no transparency."[68]

113. Similarly, the American Benefits Council has explained that PBMs conceal from insurers/health plans the amount of moneys flowing to the PBMs from drug manufacturers:

> The current rebate structure used in the marketplace is complex and opaque for many employers, making it hard for these employers as well as plan participants and beneficiaries to understand the true prices of drugs and the true value of how the rebate is calculated. While some PBMs may disclose the nature and extent of specific drug rebates, this practice varies by PBM and does not appear to be the norm across the industry.
>
> * * *
>
> Even more important to employers than excluding rebates from the discount safe harbor is the need for increased transparency by the PBM regarding the extent of discount pricing, including but not limited to, volume-based rebates that the PBM is receiving so that plans can bargain in good faith with the PBM over the PBM's retention of these amounts. This has been a desire for some in the employer community with respect to ERISA-covered plans for years. While retirement plan service providers are generally subject to upfront disclosure of the revenue they will earn with respect to a given plan pursuant to ERISA Section 408(b)(2), as well as back-end reporting to the plan on an annual basis regarding actual revenue earned, these rules do not apply to PBMs currently. Many employers believe increased transparency with respect to PBM rebates will help enable plan

[68] Hearing Before The Committee On Oversight And Government Reform House Of Representatives One Hundred Fourteenth Congress Second Session September 21, 2016, at 65-66.

> sponsors to work to recoup or otherwise retain some of these rebates for the benefit of plan participants and beneficiaries.
>
> * * *
>
> Under the current structure, many employers may not be aware of the extent of a rebate on a given drug. Even if the employer is aware of the rebate, the rebates are typically based on volume and, therefore, rebates may be provided/paid to the PBM by the manufacturer long after the drug has been sold (and the plan has been initially charged). Moreover, not all employers may have the ability to audit or account for rebates adequately.
>
> * * *
>
> As agents of the health plans with which they contract, the Council believes this PBM transparency requirement is important to ensure that the PBMs' arrangements with pharmaceutical manufacturers are aligned with the services the PBMs provide to the health plans.[69]

114. 63% of employers surveyed by the National Pharmaceutical Council expressed the view that PBMs lacked transparency in how they make money.[70]

115. PBM statements along with active concealment of information have furthered and maintained the scheme in which the Defendant Drug Manufacturers paid Defendant PBMs undisclosed bribes and kickbacks to act contrary to the

[69] *Id*. at 3, 4-5, 6, 9.

[70] National Pharmaceutical Council. Toward better value: employer perspectives on what's wrong with the management of prescription drug benefits and how to fix it, October 2017, *available at* http://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf.

interests of their insurer/health plan clients and their patient members through: (a) large rebates and fees which did not flow to the health-plan clients, and (b) huge list price increases as a vehicle to pay Defendant PBMs. Notably, even where an insurer/health plan is aware of these PBM relabeling practices, it is nonetheless unable to determine the total dollar or percentage amounts of drug company payments that the PBM retains. Indeed, PBMs refuse to disclose such information to any plan client.[71]

116. From time to time, plans seek an audit in order to ascertain whether their PBM is passing through the appropriate amount of drug company payments. During these audits, PBMs ensure that their clients remain in the dark, unable to learn the true cost of any specific drug, including Insulin. For example, PBMs require all auditors to execute an Auditor Confidentiality Agreement. These Auditor Confidentiality Agreements uniformly preclude the auditor from sharing with its (and the PBM's) plan client any drug-by-drug rebate information or the terms of any drug company rebate contract (including Defendant PBMs' contracts with the

[71] Stephan Barlas, *Employers and Drugstores Press for PBM Transparency, A Labor Department Advisory Committee Has Recommended Changes*, Pharmacy and Therapeutics (Mar. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/; *Understanding Your PBM Contract*, Pharmacy Benefit Consultants, http://pharmacybenefitconsultants.com/understand-your-pbm-contract/; David Contorno, *Lawsuit Sheds Light on PBM Fees*, Insurance Thought Leadership at *1-2 (Sept. 1, 2017), http://insurancethoughtleadership.com/lawsuit-sheds-light-on-pbm-fees/pdf/.

Defendant Drug Manufacturers). The auditor is only allowed to share the aggregate "rebate" amount the auditor ultimately concludes is owed to the plan client.[72]

117. PBMs are so secretive about their collection and distribution of drug company payments that, during an audit, PBMs, including Defendant PBMs, uniformly (i) require preapproval of the client's chosen auditor; (ii) restrict the number of drug company contracts that can be reviewed to a very limited number (typically ten); (iii) restrict the number of claims and time period that can be reviewed; (iv) refuse to allow any drug company contract to be copied; (v) require a PBM representative to sit with every auditor that is reviewing a drug company contract; and (vi) refuse to allow any auditor to copy by hand the terms of any drug company contract, among other restrictions.[73] Audits are more like spot checks — with little chance of being fulsome or independent of restrictions imposed by PBMs.

[72] Cahn, *Eliminate All PBM Contract Loopholes*; *Testimony of Susan Hayes, Hearing on PBM Compensation and Fee Disclosure*, U.S. Dep't of Labor (Aug. 20, 2014), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/AChayes082014.pdf; *PBM Compensation and Fee Disclosure*, Report to Thomas E. Perez, U.S. Secretary of Labor, U.S. Dep't of Labor (Nov. 2014), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory- council/2014ACreport1.pdf; Robert Shelley & Brian Anderson - Presenters, *PBM Contracts: How to Use Audits and Market Checks to Improve Your Bottom Line*, Atlantic Info. Servs., Inc. (Jan. 28, 2014), https://aishealth.com/sites/all/files/file_downloads/ c4p04f_012814.pdf.

[73] *Id.*

B. DISCOVERY RULE TOLLING

118. Plaintiff and the proposed Class had no way of knowing about the Defendants' scheme and deception with respect to Insulin list pricing, and no way of knowing about the Defendant Drug Manufacturers' bribing of the Defendant PBMs. Plaintiff and the proposed Class have little if any interaction with Defendant PBMs.

119. Defendant Drug Manufacturers and Defendant PBMs refuse to disclose the real reasons behind Defendant Drug Manufacturers' increased list prices for Insulin and have not until recently disclosed Defendant Drug Manufacturers' scheme to bribe Defendant PBMs by way of increased Insulin list prices.

120. Specifically, prior to October of 2016, Plaintiff and members of the proposed Class could not have discovered, through the exercise of reasonable diligence, that the Defendant Drug Manufacturers were concealing the conduct complained of herein and that the reason for their list price increases to Insulin was to bribe Defendant PBMs for favorable formulary placement.

121. Prior to October of 2016, Plaintiff and the other Class members did not discover, and did not know of facts that would have caused a reasonable person to suspect, that the Defendants were engaged in a bribery scheme using increased Insulin list prices, nor would a reasonable and diligent investigation have disclosed the true facts.

122. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule with respect to claims as to all Insulin products identified herein.

C. FRAUDULENT CONCEALMENT TOLLING

123. All applicable statutes of limitation have also been tolled by the Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the period relevant to this action.

VI. CLASS ACTION ALLEGATIONS

124. Plaintiff brings this action on behalf of itself and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3), as representative of a class defined as follows:

> All persons or entities in the United States and its territories that directly purchased Apidra, Basaglar, Fiasp, Humalog, Lantus, Levemir, Novolog, Tresiba and/or Toujeo directly from Eli Lilly, Novo Nordisk or Sanofi (the "Class").

125. The Class period is tolled to the earliest date of Defendants' initiation of the scheme described herein, wherein the Defendant Drug Manufacturers artificially inflated the list prices of their Insulins products to increase payments to Defendant PBMs in exchange for favorable formulary status. The Class period runs through the date on which the Defendant Drug Manufacturers' artificial inflation of analog Insulin drug prices ceases.

126. Excluded from the Class are defendants and their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

127. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. Plaintiff believes that the Class is over 40 in number and widely dispersed throughout the United States. Moreover, given the costs of complex litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Class is readily identifiable from information and records in the possession of Defendant Drug Manufacturers.

128. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of the Defendants. As a result of Defendants' misconduct, Plaintiff like all direct purchasers paid artificially inflated prices for analog Insulins and will continue to do so in the future.

129. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the other members of the Class.

130. Plaintiff has retained counsel experienced in the prosecution of class action litigation, who have particular experience with class action litigation involving pharmaceutical products.

131. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because the Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally-applicable conduct is inherent in the Defendants' wrongful conduct.

132. Questions of law and fact common to the Class include, but are not limited to:

a. Whether Defendant Drug Manufacturers engaged in a pattern and practice of paying illegal kickbacks and bribes, disguised as "rebates" and other sums, to Defendant PBMs, that were intended to, and did, induce the Defendant PBMs to give Defendant Drug Manufacturers' analog Insulin favorable placement on the Defendant PBMs' formularies;

b. Whether each Defendant Drug Manufacturer engaged in a fraudulent and deceptive scheme or course of conduct by improperly inflating WAC prices of their analog Insulins that Plaintiff and Class members purchased;

c. Whether Defendant Drug Manufacturers artificially inflated WAC prices of the analog Insulins;

d. Whether each Defendant Drug Manufacturer conspired with each of the Defendant PBMs for the purpose of carrying out the bribery and kickback schemes;

e. Whether the schemes caused Plaintiff and Class members to pay inflated prices for the analog Insulins;

f. Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity intended to conceal their conduct;

g. Whether Defendant Drug Manufacturers formed one-on-one enterprises with each of the Defendant PBMs for the purpose of carrying out the bribery and kickback schemes;

h. Whether Defendant Drug Manufacturers engaged in unlawful activity by paying kickbacks and bribes, and engaged in mail and/or wire fraud, in furtherance of the schemes;

i. Whether the Defendant PBMs engaged in unlawful activity by soliciting and/or accepting kickbacks and bribes, and engaged in mail and/or wire fraud, in furtherance of the scheme;

j. Whether Defendants' conduct violated RICO;

k. Whether Defendants are liable to Plaintiff and Class members for damages, measured as overcharges, from their misconduct; and

l. The amount of overcharge damages Plaintiff and the Class are owed as a result of Defendants' schemes.

133. A class action under Rule 23(b)(3) is superior to other available methods for the fair and efficient adjudication of this controversy. Such treatment will permit a large number of similarly-situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured direct purchasers a method for obtaining overcharge damages on claims that could not practicably be pursued individually, substantially

outweighs potential difficulties in management of this class action. Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

134. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. CLAIMS FOR RELIEF

COUNT ONE

VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATION ACT ("RICO"), 18 U.S.C. § 1962(c)

(Against All Defendants)

135. Plaintiff, on behalf of itself and all others similarly situated, re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this complaint.

136. 18 U.S.C. § 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity."

137. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express

Scripts and OptumRx are each "persons," as that term is defined in 18 U.S.C. § 1961(3).

138. This count alleges violations of Section 1962(c) against defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts and OptumRx, as culpable persons under RICO.

139. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

140. As alleged and described herein, Eli Lilly, Novo Nordisk, and Sanofi each formed respective association-in-fact enterprises with each of CVS Caremark, Express Scripts and OptumRx, and Defendants have conducted and/or participated in the conduct in the affairs of the RICO enterprises through a pattern of racketeering activity in violation of § 1962(c) for the purposes of carrying out their scheme, which caused Plaintiff and the Class to pay inflated prices for analog Insulin.

141. Plaintiff and the members of the Class are "persons" as defined in 18 U.S.C. §§ 1961(3) and 1964(c), have been financially injured as a result of Defendants' unlawful conduct in the form of overcharges paid for analog Insulin, and assert this count for relief pursuant to 18 U.S.C. § 1964(c).

A. THE MANUFACTURER-PBM INSULIN PRICING RICO ENTERPRISES

142. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) one of the three Defendant PBMs (CVS Caremark, Express Scripts, or OptumRx) that administers insurance coverage of the Defendant Drug Manufacturers' analog Insulins (Eli Lilly's Humalog and Basaglar, Novo Nordisk's Fiasp, Levemir, Novolog, and Tresiba, and Sanofi's Apidra, Lantus, and Toujeo), including its directors, employees, and agents, and (b) one of the Defendant Drug Manufacturers (Eli Lilly, Novo Nordisk, or Sanofi), including its directors, employees, and agents. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer-PBM Insulin Pricing Enterprises."

143. The Manufacturer-PBM Insulin Pricing Enterprises are further identified as follows.

144. **The Eli Lilly-PBM Insulin Pricing Enterprises.** The Eli Lilly-PBM Enterprises are three separate associations-in-fact, each consisting of a Defendant PBM that administers purchases of Eli Lilly's Humalog and Basaglar (including its directors, employees, and agents), and Eli Lilly (including its directors, employees and agents): (1) the Eli Lilly-CVS Caremark association-in-fact enterprise; (2) the Eli Lilly-Express Scripts association-in-fact enterprise; and (3) the Eli Lilly-OptumRx association-in-fact enterprise. Each Eli Lilly-PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and

individuals that are and have been associated for the common or shared purposes of exchanging bribes and kickbacks — falsely and misleading labeled as "rebates" — for preferred formulary positions for Eli Lilly's rapid-acting analog Insulin product, Humalog, and its long-acting analog Insulin product, Basaglar, as treatments for type 1 and 2 diabetes. Each of the Eli Lilly-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx. As to each of these Eli Lilly-PBM Enterprises, there is a common communication network by which Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx respectively share information on a regular basis. As to each of these Eli Lilly-PBM Enterprises, Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx function as continuing but separate units. At all relevant times, each of the Eli Lilly-PBM Enterprises was operated and conducted by Eli Lilly and each of the Defendant PBMs for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme.

145. **The Novo Nordisk-PBM Insulin Pricing Enterprises.** The Novo Nordisk-PBM Enterprises are three separate associations-in-fact, each consisting of a Defendant PBM that administers purchases of Novo Nordisk's Fisap, Novolog, Levemir, and Tresiba (including its directors, employees, and agents), and Novo

Nordisk (including its directors, employees and agents): (1) the Novo Nordisk-CVS Caremark association-in-fact enterprise; (2) the Novo Nordisk-Express Scripts association-in-fact enterprise; and (3) the Novo Nordisk-OptumRx association-in-fact enterprise. Each Novo Nordisk-PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanging bribes and kickbacks — falsely and misleading labeled as "rebates" — for preferred formulary positions for Nordisk's rapid-acting analog Insulin products, Novolog and Fiasp, and its long-acting analog Insulin products, Levemir and Tresiba, as treatments for type 1 and 2 diabetes. Each of the Novo Nordisk-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx. As to each of these Novo Nordisk-PBM Enterprises, there is a common communication network by which Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx respectively share information on a regular basis. As to each of these Novo Nordisk-PBM Enterprises, Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx function as continuing but separate units. At all relevant times, each of the Novo Nordisk-PBM Enterprises was operated and conducted by Novo Nordisk and the Defendant PBMs

for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme.

146. **The Sanofi-PBM Insulin Pricing Enterprises.** The Sanofi-PBM Enterprises are three separate associations-in-fact, each consisting of a Defendant PBM that administers purchases of Sanofi's Apidra, Lantus, and Toujeo (including its directors, employees, and agents), and Sanofi (including its directors, employees and agents): (1) the Sanofi-CVS Caremark association-in-fact enterprise; (2) the Sanofi-Express Scripts association-in-fact enterprise; and (3) the Sanofi-OptumRx association-in-fact enterprise. Each Sanofi-PBM Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanging bribes and kickbacks — falsely and misleading labeled as "rebates" — for preferred formulary positions for Sanofi's rapid-acting analog Insulin product, Apidra, and its long-acting analog Insulin products, Lantus and Toujeo, as treatments for type 1 and 2 diabetes. Each of the Sanofi-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx. As to each of these Sanofi-PBM Enterprises, there is a common communication network by which Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx respectively share information on a

regular basis. As to each of these Sanofi-PBM Enterprises, Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx function as continuing but separate units. At all relevant times, each of the Sanofi-PBM Enterprises was operated and conducted by Sanofi and the Defendant PBMs for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme.

147. Each of the Manufacturer-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, promoting and recommending for purchase, and administering prescriptions for analog Insulin, and deriving secret profits from these activities. These profits are greater than either the Defendant Drug Manufacturers or the Defendant PBMs could obtain absent their fraudulent concealment of the substantial "rebates" and other fees from the Defendant Drug Manufacturers to the Defendant PBMs.

148. As part of and to accomplish the common purpose of the Manufacturer-PBM Insulin Pricing Enterprises, the Defendant Drug Manufacturers systematically paid bribes and kickbacks — falsely labeled as rebates, administrative fees and/or other monies — to the Defendant PBMs in exchange for exclusive and/or favorable formulary placement. The Defendant Drug Manufacturers did so willfully, knowing

that the sales of analog Insulin were based on inflated list prices. The Manufacturer-PBM Insulin Pricing Enterprises then reported the Defendant Drug Manufacturers' list price increases to the general public, and to the respective Defendant PBM's insurer/health plan clients (and plan members), while simultaneously concealing that the true reason for the price increases was to fund bribes and kickbacks to the Defendant PBMs in exchange for formulary placement, and also to increase the dollar value of those bribes and kickbacks to increase profits to both the Defendant Drug Manufacturers and to the Defendant PBMs.

149. As outlined herein, the bribes and kickbacks paid by the Defendant Drug Manufacturers to the Defendant PBMs, which the Defendant PBMs solicited and accepted, violated the federal anti-kickback statute and various state anti-kickback statutes, as well as a number of state bribery statutes. The bribes and kickbacks paid by the Defendant Drug Manufacturers caused the Defendant PBMs to breach their duties of fidelity, and fiduciary duties, to their insurer/health plan clients (and plan members), and likewise deprived the insurers/health plans that retained the Defendant PBMs to develop, manage and administer formularies and prescription drug programs and negotiate prices with the Defendant Drug Manufacturers of the honest services of the Defendant PBMs, in that the Defendant PBMs: (a) favored the Defendant Drug Manufacturers' higher-priced analog Insulin products over lower-priced insulin products; and (b) encouraged rather than

discouraged Defendant Drug Manufacturers' price increases, both of which were contrary to the economic interests of the insurers/health plans and their plan members.

150. The Defendant Drug Manufacturers' list price increases were fraudulent, in that they were artificially inflated to fund the bribes and kickbacks, which the Manufacturer-PBM Insulin Pricing Enterprises concealed. The Manufacturer-PBM Insulin Pricing Enterprises also concealed the economic purpose of these list price increases to the Defendant Drug Manufacturers and the Defendant PBMs: the increases ultimately result in higher profits for the Defendant Drug Manufacturers, enabling them to purchase formulary access without requiring significant price reductions; and they result in higher profits for the Defendant PBMs, which earn rebates, fees and other compensation based on the Defendant Drug Manufacturers' list prices increases and sales volume. In addition, the Defendant Drug Manufacturers, as described above, realized significant increases in net profit through their substantial list prices increases, notwithstanding the increased payments (bribes and kickbacks) to Defendant PBMs necessary to secure and maintain formulary placement of Defendant Drug Manufacturers' Insulin and resulting Insulin sales.

151. Each Manufacturer-PBM Insulin Pricing Enterprise also shares a common purpose of perpetuating the use of inflated analog Insulin list prices. The

Defendant Drug Manufacturers require the inflated Insulin list prices in part to fund the bribes and kickbacks to the Defendant PBMs in exchange for favorable formulary positions. The Defendant PBMs share this common purpose because the inflated Insulin list prices increase the value of the rebates, administrative fees, and other monies they can keep, and thus increase their profits. Formulary placement determines which drugs are covered and prescribed for purchase. Given that rebates and other fees to the Defendant PBMs are determined and paid based in part on sales, the Defendant PBMs provided formulary placement to the Defendant Drug Manufacturers' analog Insulins to ensure prescriptions and sales of those Insulin products, maximizing their financial gains. As a result, the Defendant PBMs have, in concert with the Defendant Drug Manufacturers and through the respective Manufacturer-PBM Insulin Pricing Enterprises, engaged in hidden profit-making schemes, the Defendant PBMs garnering rebates and other fees and compensation from the Defendant Drug Manufacturers that the Defendant PBMs, to a significant extent, keep, and do not share with or provide to their insurer/health plan clients (or plan members). The Defendant Drug Manufacturers, meanwhile, unlawfully and fraudulently obtained sales, market share, and profits from their analog Insulins.

152. Each of the Manufacturer-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Defendant Drug Manufacturer

and each Defendant PBM that is an associate in the respective enterprise. As to each of the Manufacturer-PBM Insulin Pricing Enterprises, there is a common communication network by which each Defendant Drug Manufacturer and each PBM shares information on a regular basis, including information regarding Insulin prices. As to each of the Manufacturer-PBM Insulin Pricing Enterprises, each Defendant Drug Manufacturer and each Defendant PBM functioned as a continuing unit. At all relevant times, each of the Manufacturer-PBM Insulin Pricing Enterprises was operated for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme and its concealment.

153. At all relevant times, the Manufacturer-PBM Insulin Pricing Enterprises had an existence separate and distinct from that of its members. Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts and OptumRx are distinct corporate entities. Further, each member of the respective RICO Enterprises has an existence separate and apart from the pattern of racketeering activities of the RICO Enterprise. Each Defendant carries on distinct businesses and operations. However, as alleged and described herein, each member of each Manufacturer-PBM Insulin Pricing Enterprise was essential to the operation of the scheme conducted through Manufacturer-PBM Insulin Pricing Enterprises.

154. The Defendant PBMs, at all relevant times, have been knowing and willing participants in the conduct of the respective Manufacturer-PBM Insulin

Pricing Enterprises, and have reaped large profits from that conduct. The Defendant PBMs used their position to strike rebate deals with the Defendant Drug Manufacturers to receive bribes and kickbacks for Insulins and profit from the Defendant Drug Manufacturers' inflated list prices. The Defendant PBMs have represented to their respective insurer/health plan clients (and plan members) and the public that the rebates lower drug costs when, in fact, as the Defendant PBMs are well aware, the inflated list prices required to fund the bribes and kickbacks to them in exchange for favorable formulary placement increased drug costs, including list prices and downstream reimbursement and cost-sharing obligations of health plans and their members. In addition, as part of and to further the respective schemes, the Defendant PBMs misrepresent and/or conceal from insurer/health plan clients, plan members and the public the existence, amount and purpose of the rebates, administrative fees and/or other monies the Defendant PBMs are paid by the Defendant Drug Manufacturers as well as the effect of the rebates, administrative fees and/or other monies on Insulin list prices, and also publish, distribute and disseminate materials and information concerning Insulin list prices, net prices and the purpose of "rebates" and so-called "discounts" to conceal the Manufacturer-PBM Insulin Pricing Enterprises' schemes.

155. But for the Manufacturer-PBM Insulin Pricing Enterprises' common purpose of inflating the Defendant Drug Manufacturers' list prices to fund the bribes

and kickbacks, the Defendant PBMs would have had the incentive to disclose the fraudulent inflation of the Defendant Drug Manufacturers' list prices, and would have used their control over the management and administration of their health plan clients' formularies to penalize the Defendant Drug Manufacturers' undue price increases. By concealing this information, the Defendant PBMs and the Defendant Drug Manufacturers perpetuated the conduct of the Manufacturer-PBM Insulin Pricing Enterprises.

156. The Defendant PBMs readily participated in the scheme so that they could continue to earn money from the Defendant Drug Manufacturers that was calculated based on Insulin list price.

157. In order effectuate the scheme, each Defendant Drug Manufacturer and each Defendant PBM met on a regular basis to discuss Insulin prices, formulary position, rebates, administrative fees, other monies to the Defendant PBM, what the PBM had to do for the Defendant Drug Manufacturers in order to obtain those monies, and coordination of all of the above.

158. Further, the common communication network between each Defendant PBM and each Defendant Drug Manufacturer effectuated the purpose of implementing the list price inflation and rebate scheme and the exchange of financial rewards for the PBM activities that benefitted — and continue to benefit — the Defendant Drug Manufacturers, as well as the Defendant PBMs.

159. At all relevant times, each Defendant Drug Manufacturer and each Defendant PBM knowingly, purposefully and willingly engaged and participated in the list price inflation and rebate scheme through each Manufacturer-PBM Insulin Pricing Enterprise, and reaped substantial profits from that scheme.

160. The Manufacturer-PBM Insulin Pricing Enterprises (Eli Lilly-CVS Caremark, Eli Lilly-Express Scripts, Eli Lilly-OptumRx, Novo Nordisk-CVS Caremark, Novo Nordisk-Express Scripts, Novo-Nordisk-OptumRx, Sanofi-CVS Caremark, Sanofi-Express Scripts, and Sanofi-OptumRx) knowingly made material misrepresentations and/or omissions to the Defendant PBMs' insurer/health plan clients (and plan members) and to the general public in furtherance of the price inflation and rebate scheme regarding:

a. The reasons for the list price increases of the analog Insulins;[74]

b. The existence, purpose and amount of the rebates and other monies to the Defendant PBMs;

c. The effect of the rebates on analog Insulin list prices;

d. The effect of the rebates and other monies on the Defendant PBMs' development, management and administration of their insurer/health plan client formularies;

[74] The Eli Lilly-PBM Insulin Pricing Enterprises made these misrepresentations with respect to Humalog and Basaglar. The Novo Nordisk-PBM Insulin Pricing Enterprises made these representations with respect to Fiasp, Novolog, Levemir, and Tresiba. The Sanofi-PBM Insulin Pricing Enterprises made these misrepresentations with respect to Apidra, Lantus, and Toujeo.

e. The extent to which Defendants negotiated rebates of the analog Insulins in good faith and for a proper purpose;

f. Whether the rebates were intended to benefit insurers/health plans, plan members and/or the general public;

g. Whether the rebates lowered drug costs for insurers/health plans and plan members;

h. Whether the "preferred" formulary status of the analog Insulins reflects the drugs' safety, efficacy, or cost-effectiveness, as determined by the Defendant PBMs' formulary committees;

i. Whether the Defendant PBMs used their position regarding the development, management and administration for their own financial benefit and in contravention of the economic interests of their insurers/health plan clients (and plan members); and

j. Whether the analog Insulins would have been placed in "preferred" formulary positions absent the bribes.

161. Defendant Drug Manufacturers alone could not have accomplished the purposes of the Manufacturer-PBM Insulin Pricing Enterprises without the Defendant PBMs. For the Defendant Drug Manufacturers to profit from the scheme, the Defendant PBMs needed to convince insurers and health plans to select their formularies, on which varying analog Insulins were given favorable treatment. And the Defendant PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured lower prices. Instead, Defendant Drug Manufacturers inflated list prices and funded the bribes and kickbacks in exchange for favorable placement on the Defendant PBMs' formularies, which resulted in

increased drug costs. Without these misrepresentations, no Manufacturer-PBM Insulin Pricing Enterprise could have achieved its common purpose.

162. The impacts of the Manufacturer-PBM Insulin Pricing Enterprises are still in place as a result of Defendant Drug Manufacturers' inflated list prices. As described herein, the bribes and kickbacks are an essential part of the Manufacturer-PBM Insulin Pricing Enterprises, and are embedded in ongoing analog Insulin prices. This conduct constitutes a threat of continued criminal activity.

163. The foregoing evidences that the Defendant Drug Manufacturers and Defendant PBMs were each willing participants in the Manufacturer-PBM Insulin Pricing Enterprises, had a common unlawful and fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, *i.e.*, to increase profits for both the Defendant Drug Manufacturers and the Defendant PBMs through WAC price increases, bribes and kickbacks to the Defendant PBMs, and continued formulary status without price reductions from the Defendant Drug Manufacturers, preserving and increasing Defendant Drug Manufacturers' profits.

B. THE DEFENDANT DRUG MANUFACTURERS' USE OF THE U.S. MAILS AND INTERSTATE WIRE FACILITIES

164. During the Class period, each of the Manufacturer-PBM Insulin Pricing Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, promotion, recommendation

for purchase, and/or administration of prescriptions of the analog Insulins; the setting of the prices of the analog Insulins and price increase announcements in connection therewith; the negotiation of formulary placement, rebate, and other contracts; the transmission and/or receipt of sales and marketing literature; and/or the transmission and/or receipt of invoices, statements, and payments related to the purchase, use and/or administration of the analog Insulins. During the Class period, the Manufacturer-PBM Insulin Pricing Enterprises participated in the sale, promotion, recommendation for purchase, and administration of prescriptions for the analog Insulins throughout the United States.

165. During the Class period, Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx's illegal conduct and wrongful practices in furtherance of the Manufacturer-PBM Insulin Pricing Enterprises were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

166. The nature and pervasiveness of the Defendants' scheme, which was concertedly orchestrated out of the respective corporate headquarters of the Defendant Drug Manufacturers and the Defendant PBMs, necessarily required those Defendant Drug Manufacturers' headquarters to communicate directly and

frequently by the U.S. mails and by interstate wire facilities with the headquarters of the Defendant PBMs, and vice versa.

167. Most of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts as outlined herein) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the bribery and kickback scheme alleged herein depended upon secrecy. Defendants took deliberate steps to conceal their wrongdoing. Plaintiff can nevertheless generally describe the occasions on which the RICO predicate acts of unlawful payment of bribes and kickbacks, mail fraud, and wire fraud occurred, and how those acts were in furtherance of the list price inflation and rebate bribery and kickback scheme.

168. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the scheme involved thousands of communications throughout the Class period including, *inter alia*:

a. Marketing materials about the list prices for the analog Insulins, which Defendant Drug Manufacturers sent to Defendant PBMs and others located across the country;

b. Written and oral representations about the analog Insulin list prices that Defendant Drug Manufacturers made at least annually and, in many cases, several times during a single year;

c. Thousands of written and oral communications discussing, negotiating, conditioning, and confirming the placement of a Defendant Drug Manufacturers' analog Insulins on a particular Defendant PBM's

formulary;

d. Written and oral representations to conceal the true reasons for the Insulin list price increases and to conceal the scheme;

e. Written communications, including checks, wires and/or other payment mechanisms, relating to rebates, bribes, kickbacks, or other financial inducements paid by each of the Defendant Drug Manufacturers to each of the Defendant PBMs to induce them to place Defendant Drug Manufacturers' Insulin on the Defendant PBMs' formularies in a favorable position;

f. Written and oral communications with U.S. government agencies and health plans and insurers that fraudulently misrepresented the reasons for list price increases, or that were intended to deter investigations into the true nature of the list price increases or to forestall changes to reimbursement based on something other than list prices;

g. Written and oral communications with direct purchasers, health plans, insurers and patients concerning list prices and the reasons for increases thereof;

h. Written and oral communications by the Defendant PBMs and/or the Defendant Drug Manufacturers with health plans, insurers and patients concerning list prices and/or the reasons for increases thereof;

i. Transmission of list prices from Defendant Drug Manufacturers to third parties;

j. Receipts and payments of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities, constituting the wrongful proceeds of the list price inflation and bribery scheme; and

k. In addition to the RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their own various local headquarters or divisions, in furtherance of the price inflation and rebate scheme.

C. CONDUCT OF THE RICO ENTERPRISES' AFFAIRS

169. During the Class period, each of the Defendant Drug Manufacturers has exerted control over each Manufacturer-PBM Insulin Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, each Defendant Drug Manufacturer has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly, as follows:

a. Controlling the list prices for its analog Insulin, which determine the amount of rebates, administrative fees, and other monies each of the Defendant PBMs realizes in compensation in exchange for formulary placement;

b. Controlling Insulin list prices and increases thereof that it publicly reports and purports to explain;

c. Controlling the creation and distribution of marketing, sales, and other materials used to inform each of the Defendant PBMs of the profit potential of its analog Insulins;

d. Promoting the scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with the Defendant PBMs;

e. Providing bribes and kickbacks, falsely and misleadingly labeled as rebates or administrative fees, to induce the Defendant PBMs to place the Defendant Drug Manufacturer's analog Insulin in a favorable position on the PBM's formulary;

f. Intending that the Defendant PBMs would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that rebates lowered drug costs for insurers/health plan clients and their plan members; and

g. Publishing and announcing list price increases and the reasons therefor but concealing that the increases were to fund the bribes and kickbacks

to the Defendant PBMs to secure favorable, preferred or exclusive formulary placement.

170. Further, during the Class period, each Defendant PBM has exerted control over each Manufacturer-PBM Insulin Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, by, among other things as described herein:

a. Soliciting and/or obtaining bribes and kickbacks (falsely labeled as rebates, administrative fees, and/or other monies) in exchange for placing the Defendant Drug Manufacturer's Insulin in a favorable, preferred or exclusive position on the PBM's formularies;

b. Misrepresenting and/or concealing from insurer clients, health plan clients, plan members and the public the existence, amount, and purpose of the rebates, administrative fees and/or other monies from the Defendant Drug Manufacturers;

c. Misrepresenting and/or concealing from insurer clients, health plan clients, plan members and the public the effect of the rebates, administrative fees, and/or other monies from the Defendant Drug Manufacturers on analog Insulin list prices; and

d. Publishing, distributing and disseminating materials and information concerning Insulin list prices, net prices and/or the purpose of rebates and discounts to perpetuate and conceal the scheme.

D. DEFENDANTS' PATTERN OF RACKETEERING ACTIVITY

171. Each Defendant Drug Manufacturer and each of the Defendant PBMs has conducted and participated in the affairs of the respective Manufacturer-PBM Insulin Pricing Enterprises through a pattern of racketeering activity under 18 U.S.C.

§ 1961, and committed the following violations outlined below knowingly and with the intent to advance the scheme.

172. Defendants' pattern of racketeering has involved thousands, if not hundreds of thousands, of acts, and has occurred over a number of years.

173. All of Defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purposes. The payments of bribes and kickbacks, misrepresentations and omissions, and separate uses of the U.S. mail and/or interstate wires by Defendants and each Manufacturer-PBM Insulin Pricing Enterprise were substantially related, had similar intended purposes, involved similar participants and methods of execution, and had similar results effecting similar victims. The racketeering activity constitutes a threat of continuing criminal activity.

174. Defendants have committed the following predicate acts, all constituting racketeering activity under 18 U.S.C. § 1961.

1. <u>Violation of State Bribery Laws</u>

175. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of New Jersey. Specifically, in violation of N.J.S.A. § 2C:21-10, each Defendant Drug Manufacturer conferred benefits on each of the Defendant PBMs, which the PBMs solicited and/or accepted, in excess of

$75,000 as consideration for knowingly violating (or agreeing to violate) their duties of fidelity to their various client insurers and health plans (and the participants therein) through the rebate and administrative fee negotiations and formulary decisions and recommendations alleged above. Moreover, in violation of N.J.S.A. § 30:4D-17(c), each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the PBMs solicited and/or accepted, to obtain favorable formulary placement in connection with the furnishing of Insulin, for which payment may be made (or whose cost is or may be reported) in whole or in part under New Jersey's P.L.1968, c. 413.

176. Defendant PBMs owe a duty of fidelity to their health plan/insurance clients (and the participants and beneficiaries thereof), because of (a) the contractual relationships between each of the Defendant PBMs and their respective health plan/insurer clients and (b) the PBMs' position as agents, trustees, employees, and/or contractors for their respective health plan/insurer clients. Because of the degree of reliance, trust and confidence that the insurer/health plan clients give to Defendant PBMs in negotiating rebates and designing and implementing formulary management, each of the Defendant PBMs has such a duty of fidelity.

177. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Missouri. Specifically, in violation V.A.M.S.

§ 191.905(3), each Defendant Drug Manufacturer knowingly paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to induce the PBMs to use their control or influence over formulary design to refer insurers and health plans (and their members) to each Defendant Drug Manufacturer for the furnishing or arranging for the furnishing of Insulin.

178. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Minnesota. Specifically, in violation M.S.A. § 609.86, each Defendant Drug Manufacturer has corruptly given consideration in amounts exceeding $500 to each of the Defendant PBMs with the intent to purchase placement of its Insulin on the Defendant PBMs' formularies, which the PBMs solicited and/or accepted.

179. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Rhode Island. Specifically, in violation R.I. Gen. L. § 11-7-4, each Defendant Drug Manufacturer has corruptly given valuable consideration to each of the Defendant PBMs, and each of them, as an inducement or reward for favorable formulary placement of its Insulin on the Defendant PBMs' formularies, which the PBMs solicited and/or accepted.

180. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Alabama. Specifically, in violation of Ala. Code. § 22-1-11, each Defendant Drug Manufacturer has paid bribes to each of the Defendant PBMs, which the PBMs solicited and/or accepted, to induce the Defendant PBMs to use their control or influence over formulary design to arrange for or recommend that insurers/health plans (and their members or participants) purchase Insulin, for which payment may be made in whole or in part by the Alabama Medicaid Agency, or its agents.

181. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Connecticut. Specifically, in violation Conn. Gen. Stat. § 53a-161d, each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the PBMs solicited and/or accepted, to influence the Defendant PBMs to use their control or influence over formulary design to arrange for or recommend that insurers/health plans (and their members and participants) purchase Insulin, for which a claim of benefits or reimbursement has been filed with a local, state or federal agency.

182. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed

bribery under the laws of the State of Florida. Specifically, in violation Fla. Stat. § 409.920, each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that insurers/health plans and their participants purchase Insulin, for which product payment may be made in whole or in part under the Florida Medicaid program.

183. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Illinois. Specifically, in violation of 305 ILCS § 5/8A-3(c), each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that insurers/health plans and their participants purchase Insulin for which payment may be made in whole or in part under Illinois's Public Aid Code.

184. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Michigan. Specifically, in violation of MCLS § 400.604, each Defendant Drug Manufacturer paid bribes to each of the Defendant

PBMs, which the Defendant PBMs solicited and/or accepted, to obtain favorable formulary placement in connection with the furnishing of Insulin, for which payment may be made in whole or in part pursuant to a program established under Michigan's Act No. 280 of the Public Acts of 1939, as amended.

185. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Mississippi. Specifically, in violation of Miss. Code Ann. § 43-13-207, each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to obtain favorable formulary placement in connection with the furnishing of Insulin, for which payment may be made in whole or in part pursuant to the Medicaid program.

186. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Utah. Specifically, in violation of Utah Code Ann. § 26-20-4, each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs in excess of $1,500, which the Defendant PBMs solicited and/or accepted, to induce the purchase of Insulin, for which payment may be made in whole or in part pursuant to a Utah medical benefit program.

187. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Virginia. Specifically, in violation of Va. Code Ann. § 32.1-315(B), each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that health plans (and their participants) purchase Insulin, for which payment may be made in whole or in part under a Virginia medical assistance program.

188. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), each Defendant Drug Manufacturer and each of the Defendant PBMs has committed bribery under the laws of the State of Washington. Specifically, in violation of Rev. Code Wash. § 74.09.240, each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that health plans and their participants purchase Insulin, for which payment may be made in whole or in part under Washington public assistance or other applicable law.

2. Violation of the Travel Act: Unlawful Activity of Bribery Under State Law

189. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of New Jersey, as set forth above.

190. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Missouri, as set forth above. Moreover, and specifically in violation of V.A.M.S. § 570.150(1)(3), each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to influence the Defendant PBMs' placement of Insulin on the Defendant PBMs' formularies.

191. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful

activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Minnesota, as set forth above.

192. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Rhode Island, as set forth above.

193. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Alabama, as set forth above.

194. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Arkansas. Specifically, in violation of A.C.A. § 20-77-902(7)(A), each Defendant Drug

Manufacturer has knowingly paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that health plans and their participants purchase Insulin, for which payment may be made in whole or in part by the Arkansas Medicaid Program.

195. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Connecticut, as set forth above.

196. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Florida, as set forth above.

197. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to

intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Illinois, as set forth above.

198. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Indiana. Specifically, in violation of Burns Ind. Code Ann. § 12-17.6-6-12, each Defendant Drug Manufacturer knowingly and/or intentionally paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to refer health plans and their participants to Insulin, for which payment may be made by the Indiana Children's Health Insurance Program.

199. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Michigan, as set forth above.

200. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Mississippi, as set forth above.

201. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Utah, as set forth above.

202. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Virginia, as set forth above.

203. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each Defendant Drug Manufacturer and each of the Defendant PBMs has, in violation of

18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Washington, as set forth above.

3. Violation of the Travel Act: Unlawful Bribery Under the Anti-Kickback Act

204. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of the United States. Specifically, in violation of 42 U.S.C. § 1320a-7b(b)(2) (the "Anti-Kickback Act"), each Defendant Drug Manufacturer paid bribes to each of the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, with the intention of purchasing, and in fact purchasing, formulary placement for Insulin for which payment may be made in whole or in part under a Federal health care program. No "safe harbor" applies, because "[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price. In the Secretary's [of HHS] view, such a payment would not qualify as 'a discount or other reduction in price.'" 82 F.R. 2340, at 2340 n.1. See also id. at 2343 ("To the extent those rebates are paid to or through PBMs to buy formulary

position, such payments would not be protected by the discount statutory exemption.")

205. The Anti-Kickback Act is a criminal prohibition against payments made purposefully to induce or reward the referral or generation of federal health care business. The Anti-Kickback Act criminalizes a drug manufacturer's offer or payment of anything of value in return for a PBM's placing that manufacturer's drug in a favorable formulary position with respect to, in whole or part, a federal health care program. This includes a drug manufacturer's offer or payment to a PBM respecting private, nonfederal business that implicitly or explicitly requires that the PBM place the manufacturer's drug in a favorable position with respect to a federal health care program. The Anti-Kickback Act extends not just to a drug manufacturer's payment, but also to the solicitation or acceptance of remuneration by PBMs.

206. The OIG and the Secretary of HHS have long warned that "[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized." 68 FR 23731, at 23736 (2003).

207. The OIG and the Secretary of HHS have also stated that PBMs are not, and have never been, "buyers" within the meaning of the Anti-Kickback Act's "safe harbor" for "discounts." 82 F.R. 2340, 2343 n.36 (2019) ("the payments manufacturers retrospectively make to PBMs under rebate agreements would not

constitute discounts or other reductions in price to the extent such payments are retained by the PBM and not passed through to any buyer").

4. Mail and Wire Fraud: Deprivation of Honest Services

208. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1341, utilized the interstate mails, and have, in violation of 18 U.S.C. § 1343, utilized wires in interstate commerce, in furtherance of a scheme or artifice to defraud to deprive patients covered under plans of drug insurance, and the insurers and plans themselves, of the right of honest services, namely by each of the Defendant Drug Manufacturers paying each of the Defendant PBMs bribes and kickbacks, solicited and/or accepted by the Defendant PBMs, which, unknown to such covered patients and insurers/plans, were paid with the specific intent that they serve as payment for formulary position in such plans of drug insurance even though materially falsely and misleadingly labeled "rebates," "administrative fees," and the like, and achieved through increases in analog Insulin list prices that were falsely and misleadingly described, and which foreseeably caused Defendant PBMs, in purposeful contravention of their fiduciary duty to covered patients and insurers/plans, to change each Defendant Drug Manufacturer's Insulin position on the formulary, and intentionally caused such covered patients and others to pay more for Insulin, all in violation of 18 U.S.C. § 1346.

209. Each Defendant Drug Manufacturer paid bribes and kickbacks to each Defendant PBM in return for the Defendant PBMs violating their fiduciary duties by using their control and/or influence over formulary decisions to favor the Drug Manufacturer Defendants' higher-priced analog Insulin instead of lower-priced drugs, even though that was contrary to the interests of the health plan/insurer principals who retained the Defendant PBMs.

210. The federal and state anti-kickback statutes discussed above make it illegal for Defendant PBMs to receive rebates, administrative fees, or other moneys in exchange for formulary placement if such payments are not passed along as purchase discounts and disclosed to the federal government. These statutes impose upon the Defendant PBMs a duty of honest services when negotiating rebates, which requires (at a minimum) that Defendant PBMs disclose that they are receiving kickbacks in exchange for recommending and promoting higher-priced drugs over lower-priced drugs indicated for the same uses.

211. Because of the degree of discretionary control that the each Defendant PBM's clients have over the negotiation of rebates, Defendant PBMs act as either common-law agents and/or trustees in the negotiation of rebates regarding their clients' drug purchases. As common-law agents and/or trustees in the negotiation of rebates regarding their clients' drug purchases, each of the Defendant PBMs has duties of fidelity and honesty to not misuse its negotiating powers in a manner that

is contrary to, and harmful to, its clients' interests. It is contrary to these duties for a PBM to use its negotiating power to receive rebates, administrative fees, and other monies by inducing manufacturers to increase list prices of Insulin, which price increases are detrimental to the Defendant PBMs' clients.

212. Furthermore, in making recommendations and decisions regarding the design, implementation, and administration of their clients' formularies (including the addition and deletion of drugs on the clients' formularies and changes in drugs' position on their clients' formularies) the Defendant PBMs act as common-law agents for their clients. In cases that the Defendant PBMs have final, discretionary control over the design and structure of their clients' formularies, the Defendant PBMs act as common-law trustees. As common-law agents and/or trustees regarding the design, implementation, and administration of their clients' formularies, each of the Defendant PBMs has duties of fidelity and honest services in the Defendant PBMs' design, implementation, and administration of their clients' formularies.

213. Each Defendant PBM's discretionary control and authority over its own compensation, including control over the inputs to that compensation, make it a functional fiduciary under common-law trustee principles. This fiduciary control and authority arise by virtue of the PBM's ability to negotiate the size of the payments it receives, and to assign various labels and classifications to the payments.

The label Defendant PBMs apply to a particular payment, or portion thereof, determines the amount retained by the PBM for its own account as opposed to the amount, if any, remitted to the insurer/health plan. Even if, in some instances, Defendant PBMs pass 100% of certain "rebates" through to their clients, Defendant PBMs have applied different labels to certain payments (or portions thereof) to conceal and retain a significant portion of the payments they receive from drug manufacturers (including each Defendant Drug Manufacturer), which are hidden from or undisclosed to the PBM's client. By dictating the amount of the payments they receive from drug manufacturers, and ultimately keeping it for themselves, Defendant PBMs set their own compensation for services.

5. Mail Fraud

214. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1341, used the U.S. mails in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. Specifically, as outlined above, each Defendant Drug Manufacturer's Insulin has been promoted through the mails, thereby announcing to insurers, health plans and patients each Defendant Drug Manufacturer's list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Defendant Drug Manufacturer's bribes and kickbacks to each of the Defendant

PBMs to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the bribes and kickbacks to the Defendant PBMs "rebates" — which have been publicly represented as lowering drug costs — when they are, in fact, bribes and kickbacks for formulary placement, which enabled each Defendant Drug Manufacturer to sell Insulin at inflated prices.

215. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails in furtherance of their schemes.

6. Wire Fraud

216. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1343, transmitted or caused to be transmitted by means of wire, radio, or television communication in interstate commerce, in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. Specifically, as outlined above, each Defendant Drug Manufacturer's Insulin has been promoted through electronic means, thereby announcing to insurers, health plans and patients its list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Defendant Drug Manufacturer's bribes and kickbacks to each of the Defendant PBMs to secure formulary placement. Moreover, Defendants have falsely and misleadingly called

the bribes and kickbacks to the Defendant PBMs "rebates" — which have been publicly represented as lowering drug costs — when they are, in fact, bribes and kickbacks for formulary placement, which enabled each Defendant Drug Manufacturer to sell Insulin at inflated prices.

217. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of interstate wires in furtherance of their schemes

E. HARM CAUSED BY THE DEFENDANTS' BRIBERY, KICKBACK AND FRAUD SCHEME

218. Defendants' violations of federal and state law and their pattern of racketeering activity have directly and proximately caused Plaintiff and members of the Class to be injured in their business or property by overpaying for Defendant Drug Manufacturers' analog Insulin. Plaintiff and the Class directly purchase Insulin from the Defendant Drug Manufacturers, and thus were directly and immediately harmed Defendants' schemes. Each of the Defendant Drug Manufacturers and each of the Defendant PBMs intended and foresaw that Plaintiff and members of the Class would, by paying list prices for analog Insulin, pay substantial overcharges due to Defendants' pattern of racketeering activity.

219. During the Class period, Defendant Drug Manufacturers paid bribes and kickbacks to the Defendant PBMs in exchange for preferred formulary placement in order to maintain and/or increase sales and profits.

220. Though the Defendant PBMs could have used their control over the development, management, and administration of the formularies and prescription drug programs that their client insurers/health plans relied upon to drive down the prices for Insulin by forcing Defendant Drug Manufacturers to lower their list prices, the Defendant PBMs instead leveraged their position to obtain Defendant Drug Manufacturers' bribes and kickbacks for their own financial benefit and contrary to the economic interests of their insurer/health plan clients and plan members.

221. Rather than lower their prices to gain market share via formulary inclusion, Defendant Drug Manufacturers instead engaged in a scheme with the Defendant PBMs to corrupt the supply chain by artificially inflating list prices in exchange for preferred formulary placement, shifting the cost of the bribes and kickbacks to direct purchasers of Insulin such as Plaintiff and the Class and sharing those financial benefits with the Defendant PBMs.

222. Plaintiff and the Class are the only purchasers of Insulin directly from Defendant Drug Manufacturers, and were directly harmed by Defendant Drug Manufacturers' price inflation and rebate schemes with the Defendant PBMs.

223. Absent the payment of bribes and kickbacks, and their achievement through Insulin list price increases, Defendant Drug Manufacturers would have been forced to compete for preferred formulary placement through lower prices, as they would in a legitimate market. As the gatekeepers in the supply chain, the Defendant

PBMs could and would have used formulary placement (or exclusion) to penalize manufacturers who raised prices as Defendant Drug Manufacturers did here, rather than perversely rewarding manufacturers who raised prices and inducing them to do so with favorable formulary placement.

224. But for the payment of bribes and kickbacks, and their achievement through Insulin list price increases, Defendant Drug Manufacturers' Insulin would have had a lower list price, and Plaintiff would have paid less for Defendant Drug Manufacturers' Insulin. Plaintiff and Class members have overpaid hundreds of millions of dollars for Insulin purchased directly from Defendant Drug Manufacturers based on inflated list prices.

225. Defendants' racketeering activity directly and proximately caused Plaintiff's injuries because Plaintiff and the Class members were and are the initial and only direct purchasers of analog Insulin from the Defendant Drug Manufacturers. Further, given that Plaintiff and the Class members were and are the most direct and immediate victims of the unlawful and fraudulent schemes, Plaintiff and the Class members are best situated to vindicate the law and seek recovery for the economic harm caused by Defendants based on the substantial overcharges for analog Insulin, which only Plaintiff and the Class members paid.

226. By virtue of these violations of 18 U.S.C. § 1962(c), pursuant to 18 U.S.C. § 1964(c), Defendants are, respectively, jointly and severally liable to

Plaintiff and members of the Class for three times the overcharges that Plaintiff and Class members have paid, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT TWO

VIOLATIONS OF RICO, 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)

(Against All Defendants)

227. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

228. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

229. Each Defendant Drug Manufacturer and each of the Defendant PBMs has violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of the respective conspiracies has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Manufacturer-PBM Insulin Pricing Enterprises described previously through a pattern of racketeering activity.

230. As set forth in detail above, Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting a pattern of racketeering activity, in furtherance of the conspiracy. Defendants intended to

engage in the schemes resulting in Plaintiff and the Class members paying substantial overcharges for Defendant Drug Manufacturers' analog Insulin. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes outlined herein.

231. The nature of the Defendants' acts, material misrepresentations and omissions in furtherance of the conspiracy, as set forth in detail above, gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their ongoing unlawful and fraudulent acts have been and are part of an overall pattern of racketeering activity.

232. Defendants have engaged (and continue to engage) in the commission of overt acts in furtherance of the Manufacturer-PBM Insulin Pricing Enterprise schemes, including the following unlawful racketeering predicate acts (as outlined in detail above):

a. Multiple instances of unlawful bribery and kickbacks in violation of 18 U.S.C. § 1952 and various federal and state laws comprising racketeering activity under 18 U.S.C. § 1961;

b. Multiple instances of honest services fraud/deprivation under 18 U.S.C. § 1346;

c. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341; and

d. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343.

233. Defendants' violations of the above federal and state laws and the effects thereof outlined in detail above are continuing and will continue. As a direct and proximate result of these violations, Plaintiff and members of the Class have been injured in their business and property; Plaintiff and Class members have made hundreds of millions of dollars in overpayments for Insulin purchased directly from the Defendant Drug Manufacturers that they would not have paid but for the Defendants' conspiracies to violate 18 U.S.C. § 1962(c).

234. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are, respectively, jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully demands that this Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare Plaintiff as the representatives of the Class;

B. Enter judgments against the Defendants and in favor of the Plaintiff and the Class;

C. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial pursuant to 18 U.S.C. § 1964(c);

D. Award the Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: March 31, 2020

Respectfully submitted,

ROCHESTER DRUG CO-OPERATIVE, INC.

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